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UNITED STATES DISTRICT COURT
DISTRICT OF UTAH, CENTRAL DIVISION

IN RE POLARITYTE, INC. SECURITIES LITIGATION, **THIS DOCUMENT RELATES TO:** **All Actions**	Master File No. 2:18-cv-00510-JNP (Consolidated with 2:18-cv-00514-DB) District Judge Jill Parish **AMENDED CLASS ACTION COMPLAINT FOR VIOLATION OF THE FEDERAL SECURITIES LAWS** **JURY TRIAL DEMANDED**

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Lead Plaintiff Yedid Lawi ("Plaintiff"), individually and on behalf of all other persons similarly situated, by Plaintiff's undersigned attorneys, for Plaintiff's amended complaint against Defendants (defined below), alleges the following based upon personal knowledge as to Plaintiff and Plaintiff's own acts, and information and belief as to all other matters, based upon, *inter alia*, the investigation conducted by and through Plaintiff's attorneys, which included, among other things, a review of the Defendants' public documents, conference calls and announcements made by Defendants, United States Securities and Exchange Commission ("SEC") filings, wire and press releases published by and regarding PolarityTE, Inc. ("PolarityTE" or the "Company"), analysts' reports and advisories about the Company, and information readily obtainable on the Internet. Plaintiff believes that substantial evidentiary support will exist for the allegations set forth herein after a reasonable opportunity for discovery.

I. NATURE OF THE ACTION

1. This is a federal securities class action on behalf of a class consisting of all persons other than Defendants who purchased or otherwise acquired PolarityTE securities between April 7, 2017 and March 15, 2019, both dates inclusive (the "Class Period"). Plaintiff seeks to recover compensable damages caused by Defendants' violations of the federal securities laws and to pursue remedies under Sections 10(b) and 20(a) of the Securities Exchange Act of 1934 (the "Exchange Act") and Rule 10b-5 promulgated thereunder.

2. PolarityTE purports to be a commercial-stage biotechnology and regenerative biomaterials company focused on discovering, designing and developing a range of regenerative tissue products and biomaterials for the fields of medicine, biomedical engineering and material sciences. The Company's leading product is SkinTE, which is intended to be used by physicians or other appropriate healthcare providers for homologous uses of skin tissues/integument. PolarityTE claims that patients who have suffered from an event, disease, process or acquired

deficit that results in the functional loss or void of skin/integument systems can receive SkinTE as an adjunct and/or in place of split-thickness skin grafting, full-thickness grafting, temporizing skin coverage and/or skin substitute products.

3. PolarityTE is the latest iteration of a public company that has morphed six times. In its prior iteration, when the company was named Majesco Entertainment Holdings ("Majesco"), it received backing by a group of "fraudsters," including, the Company's former Chief Financial Officer ("CFO") Defendant John Stetson ("Stetson"), along with Barry Honig ("Honig") and Michael Brauser ("Brauser"), both of whom are 7% shareholders of PolarityTE. These fraudsters were recently charged by the SEC for orchestrating "pump and dump" schemes in three unrelated companies. These fraudsters were also behind a reverse-merger that brought PolarityTE public.

4. On December 7, 2016, Majesco filed a Form 8-K disclosing that on December 1, 2016, it had entered into an Agreement and Plan of Reorganization ("the Agreement") with Majesco Acquisition Corp., a Nevada corporation and wholly-owned subsidiary of Majesco and PolarityTE, and Dr. Denver Lough ("Lough") the owner of 100% of the issued and outstanding shares of capital stock of PolarityTE.

5. As discussed further below, due to the involvement of these "fraudsters" in PolarityTE, the SEC also recently opened an investigation into the Company, and has filed a formal order of investigation against Honig, Stetson and Brauser into potential violations of the anti-fraud and other provisions of the Securities Act, the Exchange Act and SEC rules promulgated thereunder by writing, or causing to be written, false or misleading promotional articles, engaging in a variety of other manipulative trading practices as well as filing false reports of their beneficial ownership or failure to file reports of their beneficial ownership when required to do so, in connection with PolarityTE.

Defendants' False Statements About The SkinTE Patent Application

6. The Class Period begins on April 7, 2017, when PolarityTE announced the closing of the Agreement through which the Company purchased Lough's pending patent application #14/954,335 ("the November 2015 SkinTE Patent Application") in exchange for over $104 million of PolarityTE stock ("the Merger"). One week prior, on March 31, 2017, the U.S. Patent and Trademark Office ("USPTO") posted on the November 2015 SkinTE Patent Application's website its decision to issue a Non-Final Rejection of the patent. The USPTO mailed the Non-Final Rejection letter on April 7, 2017—the same day of the Merger.

7. Additionally, on April 7, 2017 PolarityTE filed an 8-K with the SEC that stated that "Polarity[te] NV is the owner of a novel regenerative medicine and tissue engineering platform developed and *patented* by Dr. Lough," and on a FOX Business interview published on October 24, 2017, Defendant Lough publicly misrepresented the technology, stating that "[w]e found out this was sort of a novel technology, and, we ended up patenting it and being approached by a variety of investors." These statements were materially misleading.

8. Over the next several months, PolarityTE issued various statements about the SkinTE product and/or patent applications, as well as statements discussing intellectual property risks generally, that failed to disclose the fact that PolarityTE had received a Non-Final Rejection of the November 2015 SkinTE Patent Application.

9. On October 25, 2017, *Seeking Alpha* published an article by White Research, titled, "PolarityTE: A Comprehensive Look at The Bull Vs. Bear Cases", finally exposing PolarityTE's contradictory, misleading and flipflopping statements, at times stating that the Company had a "patented technology" and at other times stating it had a "patent application."

10. Following the disclosures in the *Seeking Alpha* article, PolarityTE's share price fell $0.98, or 3.94%, over a two-day decline, to close at $23.92 on October 26, 2017.

11. On June 4, 2018, the USPTO issued a Final Rejection for the November 2015 SkinTE Patent Application. The same day, PolarityTE announced an offering of 2.1 million shares priced at $25.50 per share.

12. On June 5, 2018, PolarityTE entered into an underwriting agreement with Cantor Fitzgerald relating to the issuance and sale of the Company's common stock. In the underwriting agreement, PolarityTE failed to disclose that it had received a Final Rejection from the USPTO for the November 2015 SkinTE Patent Application.

13. On June 25, 2018, *Citron Research* published a report exposing the Defendants' failure to disclose the USPTO's March 31, 2017 notice of Non-Final rejection of the 2015 SkinTE Patent Application and the USPTO's June 4, 2018 Final Rejection.

14. On this news, PolarityTE's share price fell $12.32, or 31.81%, over a two-day decline, to close at $26.40 on June 26, 2018.

15. On June 27, 2018, PolarityTE issued a press release, acknowledging for the first time that it had received Non-Final and Final Rejections of the November 2015 SkinTE Patent Application.

16. On this news, PolarityTE's share price fell another $3.35, or 12.68%, to close at $23.06 on June 27, 2018.

The SEC Action Against Unrelated Entities And The Investigation Of The Company

17. On September 7, 2018, the SEC filed a complaint in the U.S. District Court for the Southern District of New York alleging that certain persons, including former CFO Stetson, manipulated the price of securities of three unrelated public companies. Defendant Stetson was subsequently terminated by PolarityTE.

18. On this news, PolarityTE's share price fell $3.92, or 16.03%, to close at $20.54 on September 7, 2018.

19. In October 2018, PolarityTE received a document request and inquiries from the SEC relating to subjects addressed in short seller reports, including *Citron Research*.

20. On March 4, 2019, PolarityTE received notice that the SEC opened a formal investigation of the Company for possible violations of securities laws, including the anti-price manipulation provisions of the Exchange Act, regarding its public disclosures and ownership. It also received a subpoena on March 1, 2019 requesting additional documents related to communications between the company and others, which were identified in the SEC Complaint filed on September 7, 2018, including Honig, Defendant Stetson, and Brauser, the Merger, its regenerative medicine business, including SkinTE, and any promotion of the Company or its securities.

21. On March 18, 2019, PolarityTE disclosed the SEC investigation and subpoena in its Form 10-KT filing.

22. Following the disclosure in the March 18, 2019 10-KT, PolarityTE's share price fell $3.39, or 21.91%, over a three-day decline, to close at $12.08 on March 20, 2019.

Defendants Failed To Disclose Form 483 Violations

23. The SkinTE product, and its manufacturing facilities, are required to comply with current good tissue practices ("cGTPs"). PolarityTE's facilities are subject to FDA inspections. The FDA issues Form 483 to management at the conclusion of an inspection when investigators have observed any conditions that in their judgment may constitute violations of the Food Drug and Cosmetic (FD&C) Act and related Acts.

24. On July 13, 2018, at the conclusion of an FDA inspection of the Company's facilities where SkinTE was manufactured, PolarityTE received a Form 483. The Form 483 noted eight separately observed violations of FDA regulations regarding cGTPs. The violations noted PolarityTE's complete lack of controls in the manufacture of the SkinTE product.

25. On September 12, 2018, PolarityTE conducted a conference call with analysts to discuss PolarityTE's 3Q 2018 results. While touting PolarityTE's state of the art manufacturing facilities, Defendant Lough failed to disclose that the same Salt Lake City facility where they were manufacturing the SkinTE product had received a Form 483 with eight noted violations.

26. On September 13, 2018, Defendant Lough spoke at the Morgan Stanley Health Conference. Defendant Lough stated that the Company had "very clean rooms" and "an assembly line mechanism in order for us to maintain the absolute utmost aseptic technique". Again, Defendant Lough failed to disclose the receipt of the Form 483.

27. On September 25, 2018, *The Capitol Forum*, a $24,000/year subscription news service with an undetermined number of subscribers, published an article with the headline, "PolarityTE: FDA Form 483 Raises Issues with SkinTE Processing and Operations." The content available to the non-subscribing public stated: "The FDA has identified issues at PolarityTE's (PTE) SkinTE facility that may violate the Food Drug and Cosmetic Act, according to a Form 483 that was issued to PolarityTE after the FDA conducted an inspection of the facility between July 9 and 13, 2018."

28. On this news, PolarityTE's share price fell $2.80, or 12.87%, over a two-day decline, to close at $18.95 on September 26, 2018.

29. On October 18, 2018, *Citron Research* published a report titled: "PolarityTE: This Game Is Over! Price Target - $2 The FDA Has Spoken!" In addition to reporting that PolarityTE received a Form 483, *Citron Research* included a link to the actual Form 483 which detailed the eight FDA observations of violations of FDA regulations.

30. Following the disclosures in the *Citron Research* report, PolarityTE's share price fell $2.49, or 17.05%, to close at $12.11 on October 18, 2018.

Defendants Falsely Touted Registration Under Section 361

31. On October 3, 2017, PolarityTE issued a press release announcing that it had registered SkinTE with the FDA pursuant to Section 361 of the Public Health Service Act ("Section 361"). A product can be regulated *solely* under Section 361 if it is a human cells, tissues, and cellular and tissue-based product ("HCT/P") that meets certain criteria under Title 21 CFR 1271: (1) is minimally manipulated; (2) is intended for homologous use only; and (3) the manufacture of the HCT/P must not involve the combination of the product with other substances except for certain discreet exceptions. Many skin products and fake tissue products have registered under Section 361 yet have never gained FDA approval.

32. The SkinTE product objectively failed to meet any of three requirements for Section 361 regulation. Yet, Defendants repeatedly indicated to investors throughout the Class Period that SkinTE was eligible for regulation under Section 361, which would allow PolarityTE to avoid the expensive and burdensome 10 year plus process of undergoing clinical trials on human patients and presenting this data to the FDA to gain its stamp of approval. Instead, by registering under Section 361, Defendants were able to take their product straight to market. But Defendants knew that SkinTE does not qualify for registration solely under Section 361.

33. On July 20, 2018, *Seeking Alpha* published an article by *Research Noir* titled, "Citron Just Scratched The Surface: Material Omissions and False Claims From PolarityTE," exposing the fact that the SkinTE product did not meet, and couldn't possibly have met, the requirements for regulation under Section 361 because the product did not meet the "minimally manipulated" and "not combined with another article" prongs necessitated for regulation *solely* under Section 361. Defendants' prior statements regarding SkinTE's regulation under Section 361 omitted material facts, were imbedded with untrue material facts, and lacked a factual basis.

34. On July 23, 2018, *Ozgur Ogut* published an article titled, "SkinTE and the FDA's 361 Pathway" further exposing the fact that the SkinTE product did not meet regulation under Section 361, because the product – in addition to not meeting the "minimally manipulated" and "not combined with another article" prongs – also did not meet the "homologous use" prong.

35. Following disclosures in the *Seeking Alpha* and *Ozgur Ogut* articles, PolarityTE's share price fell $2.54, or 12.41%, over the following two trading sessions, to close at $17.93 on July 23, 2018.

36. As a result of Defendants' wrongful acts and omissions, and the precipitous decline in the market value of the Company's common shares, Plaintiff and other Class members have suffered significant losses and damages.

II. JURISDICTION AND VENUE

37. The claims asserted herein arise under and pursuant to §§10(b) and 20(a) of the Exchange Act (15 U.S.C. §§78j(b) and §78t(a)) and Rule 10b-5 promulgated thereunder by the SEC (17 C.F.R. §240.10b-5).

38. This Court has jurisdiction over the subject matter of this action under 28 U.S.C. §1331 and §27 of the Exchange Act.

39. Venue is proper in this Judicial District pursuant to §27 of the Exchange Act (15 U.S.C. §78aa) and 28 U.S.C. §1391(b) as PolarityTE's principal executive offices are located within this Judicial District.

40. In connection with the acts, conduct and other wrongs alleged in this Complaint, Defendants, directly or indirectly, used the means and instrumentalities of interstate commerce, including but not limited to, the United States mail, interstate telephone communications and the facilities of the national securities exchange.

III. PARTIES

41. Lead Plaintiff Yedid Lawi purchased PolarityTE securities at artificially inflated prices during the Class Period and was damaged upon the revelation of the alleged corrective disclosures.

42. Defendant PolarityTE is incorporated in Delaware, and the Company's principal executive offices are located at 123 Wright Brothers Drive, Salt Lake City, UT 84116. Until September 18, 2018, PolarityTE traded under the NASDAQ ticker symbol "COOL". PolarityTE's common stock now trades on the NASDAQ under the ticker symbol "PTE."

43. Defendant PolarityTE billed itself as "an entirely new and radically unique regenerative medicine company committed to developing the first forms of functionally-polarized autologous tissues for use in medical procedures requiring reconstructive applications by surgeons and wound care specialists."

44. PolarityTE was founded by Defendant Lough and Dr. Edward Swanson ("Swanson"), who worked as residents in plastic and reconstructive surgery at Johns Hopkins University School of Medicine and left to form the Company.

45. Defendant Lough has served at all relevant times as PolarityTE's Chief Executive Officer ("CEO"), Chief Scientific Officer, and Chairman of the Board of Directors.

46. Defendant John Stetson ("Stetson") served as PolarityTE's CFO until June 20, 2018, when he was appointed as Chief Investment Officer and President of the Company's newly formed strategic development office, PolarityIS. On September 7, 2018, after he was named a defendant in a suit brought by the SEC, Defendant Stetson was terminated by the Company.

47. The Defendants referenced above in ¶¶ 45-46 are sometimes referred to herein collectively as the "Individual Defendants."

48. The Individual Defendants possessed the power and authority to control the contents of PolarityTE's SEC filings, press releases, and other market communications. The Individual Defendants were provided with copies of the Company's SEC filings and press releases alleged herein to be misleading prior to or shortly after their issuance and had the ability and opportunity to prevent their issuance or to cause them to be corrected. Because of their positions with the Company, and their access to material information available to them but not to the public, the Individual Defendants knew that the adverse facts specified herein had not been disclosed to and were being concealed from the public, and that the positive representations being made were then materially false and misleading. The Individual Defendants are liable for the false statements and omissions pleaded herein.

IV. MATERIALLY FALSE AND MISLEADING STATEMENTS ISSUED DURING THE CLASS PERIOD

49. On March 31, 2017, the USPTO posted the Non-Final Rejection of PolarityTE's November 2015 SkinTE Patent Application on "PAIR," the USPTO's website for viewing the status of patent applications. *See* § VI. B. 4. After the Non-Final Rejection, PolarityTE withdrew all but four of its original 37 claims. As to the four remaining claims, the USPTO concluded that they failed the written description requirement and were also deemed "obvious" in light of three prior publications.

50. The Class Period begins on April 7, 2017 with Defendants' first public statements following the posting of the Non-Final Rejection of the November 2015 SkinTE Patent Application.

Second Quarter Fiscal Year 2017 (February 1, 2017-April 30, 2017)

51. On April 7, 2017, PolarityTE filed a Form 8-K with the SEC, signed by Defendant Stetson, announcing the completion of the Merger. The report stated that Polarityte

NV, the Company's wholly owned subsidiary, "is the owner of a novel regenerative medicine and tissue engineering platform developed and **patented** by Dr. Lough." (Emphasis supplied.)

52. The statement referenced in ¶ 51 is materially false and/or misleading because it misrepresented and/or failed to disclose the following adverse facts pertaining to the Company's business and operations which were known to Defendants or recklessly disregarded by them: (i) there was no patented platform; and (ii) the USPTO had already issued a notice of Non-Final rejection of the November 2015 SkinTE Patent Application.

53. On April 27, 2017, Defendant Lough again falsely represented that PolarityTE had a patent when he made the following statement in an interview with BioInformant (emphasis supplied): "That's a loaded question and **being a public company with patented and proprietary materials,** I can't go into too much detail...."

54. The statements referenced in ¶ 53 are materially false and/or misleading because they misrepresented and/or failed to disclose the following adverse facts pertaining to the Company's business and operations which were known to Defendants or recklessly disregarded by them: (i) PolarityTE was not the owner of a patent; and (ii) the USPTO had already issued a notice of Non-Final rejection of the November 2015 SkinTE Patent Application.

Third Quarter Fiscal Year 2017 (May 1, 2017-July 31, 2017)

55. On June 8, 2017 PolarityTE filed a Form 8-K with the SEC, signed by Defendant Stetson, with an attached press release. The press release announced pre-clinical results for the SkinTE product and claimed that it is an **"autologous homologous SkinTE™ construct."**

56. The statements referenced in ¶ 55 were materially false and/or misleading because they misrepresented and/or failed to disclose that SkinTE was not autologous or homologous as defined by the FDA in Section 361, which was known to Defendants or recklessly disregarded by them.

57. The June 8, 2017 press release also stated (emphasis supplied): "The Company's novel regenerative medicine and tissue engineering platform was developed **and patented** by chairman and chief executive officer, Denver Lough M.D., Ph.D."

58. The statements referenced in ¶ 57 were materially false and/or misleading because they misrepresented and/or failed to disclose the following adverse facts pertaining to the Company's business and operations which were known to Defendants or recklessly disregarded by them: (i) PolarityTE was not the owner of a patented platform; and (ii) the USPTO had already issued a notice of Non-Final rejection of the November 2015 SkinTE Patent Application.

59. On June 8, 2017, PolarityTE held a Conference Call at the Future of Skin Regeneration Conference. On the call, Defendant Lough made specific statements touting the alleged success of SkinTE, and its underlying technology, while never disclosing the Non-Final Rejection of the November 2015 SkinTE Patent Application, its leading product. On the call, Defendant Lough stated (emphasis supplied): "[T]he purpose of today's call is to follow-up on today's press release announcing some revolutionary data from our lead **autologous, homologous SkinTE construct** for regenerative skin applications and burns wounds and scar treatment efforts."

60. The statements referenced in ¶ 59 were materially false and/or misleading because they misrepresented and/or failed to disclose the following adverse facts pertaining to the Company's business and operations which were known to Defendants or recklessly disregarded by them: (i) the USPTO had already issued a notice of Non-Final rejection of the November 2015 SkinTE Patent Application; and (ii) SkinTE was not autologous or homologous as defined by the FDA in Section 361.

61. On June 9, 2017, PolarityTE filed a Form 10-Q with the SEC, for the quarterly period ended April 30, 2017, signed by Defendants Lough and Stetson (the "June 9, 2017 10-

Q"). The June 9, 2017 10-Q contained signed certifications by Defendants Lough and Stetson pursuant to Section 302 of the Sarbanes-Oxley Act of 2002 ("SOX"), stating that they both reviewed the quarterly report and "[b]ased on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading. . . ."

62. The June 9, 2017 10-Q stated (emphasis supplied), "**Dr. Lough is the named inventor under a pending patent application** for a novel regenerative medicine and tissue engineering platform filed in the United States and elsewhere."

63. The statement referenced in ¶ 62 was materially false and/or misleading because it misrepresented and/or failed to disclose the following adverse facts pertaining to the Company's business and operations which were known to Defendants or recklessly disregarded by them: (i) the USPTO had already issued a notice of Non-Final rejection of the November 2015 SkinTE Patent Application, the Company's leading product; and (ii) the Company knew there was a substantial likelihood that the Company's engineering platform would never receive a patent.

Fourth Quarter and End of 2017 Fiscal Year (August 1, 2017-October 31, 2017)

64. On September 14, 2017, PolarityTE filed a Form 10-Q with the SEC for the quarterly period ended July 31, 2017, signed by Defendant Lough and Defendant Stetson ("the September 14, 2017 10-Q"). The September 14, 2017 10-Q also contained the same Section 302 SOX certifications by Defendants Lough and Stetson referenced in ¶ 61. The September 14, 2017 10-Q repeated the statement that "**Dr. Lough is the named inventor under a pending patent application** for a novel regenerative medicine and tissue engineering platform filed in the United States and elsewhere." (Emphasis supplied.)

65. The statement referenced in ¶ 64 was materially false and/or misleading because it misrepresented and/or failed to disclose the following adverse facts pertaining to the Company's business and operations which were known to Defendants or recklessly disregarded by them: (i) the USPTO had already issued a notice of Non-Final rejection of the November 2015 SkinTE Patent Application, the Company's leading product; and (ii) the Company knew there was a substantial likelihood that the Company's engineering platform would never receive a patent.

66. On October 3, 2017, PolarityTE issued a press release "announc[ing] FDA Registration of Lead Product – SkinTE." The press release stated (emphasis supplied):

> PolarityTE™, Inc. (NASDAQ:COOL) **today announced that the Company's lead product, SkinTE™, has been registered with the U.S. Food and Drug Administration (FDA) pursuant to applicable regulations governing human cells, tissues, and cellular and tissue-based products (HCT/Ps). SkinTE™ is an autologous, minimally manipulated construct intended for homologous uses of skin tissues.**
>
> **"The FDA registration of SkinTE™ is an important regulatory step that sets the stage for commercialization and a staged market entry of this revolutionary technology into clinical application," said Denver M. Lough**, M.D., Ph.D., Chief Executive Officer of PolarityTE™.
>
> About SkinTE™ and FDA Tissue Establishment Registration
> **SkinTE™ is regulated by the FDA as an HCT/P solely under Section 361 of the Public Health Service Act and 21 CFR 1271.**

67. The statements referenced in ¶ 66 were materially false and/or misleading because they misrepresented and/or failed to disclose that SkinTE was not autologous or homologous as defined by the FDA in Section 361 and therefore not eligible for regulation solely under Section 361, which was known to Defendants or recklessly disregarded by them.

68. During a FOX Business interview published on October 24, 2017, Defendant Lough publicly misrepresented that the technology underlying the Company's SkinTE process—*i.e.*, the November 2015 SkinTE Patent Application —was already patented, stating that "[w]e

found out this was sort of a novel technology, **and, we ended up patenting** it and being approached by a variety of investors." (Emphasis supplied.)

69. The statement referenced in ¶ 68 was materially false and/or misleading because Defendant Lough misrepresented and/or failed to disclose the following adverse facts pertaining to the Company's business and operations which were known to Defendants or recklessly disregarded by them: (i) PolarityTE was not the owner of a patented platform; (ii) the USPTO had already issued a notice of Non-Final rejection of the November 2015 SkinTE Patent Application; and (iii) the Company knew there was a substantial likelihood that the Company's engineering platform would never receive a patent.

First Quarter Fiscal Year 2018 (November 1, 2017-January 31, 2018)

70. On November 1, 2017, PolarityTE filed a Form 8-K with the SEC, signed by Defendant Stetson, with an attached press release in which the Company discussed intellectual property risks in generic terms, while never disclosing the Non-Final Rejection for the November 2015 SkinTE Patent, its leading product (emphasis supplied):

> **We cannot ensure that any of the pending patent applications we acquire, have acquired, or may file will result in issued patents**. Competitors may be able to design around our patents or develop procedures that provide outcomes that are comparable or even superior to ours…**The failure to obtain and maintain patents and/or protect our intellectual property rights could have a material and adverse effect on our business, results of operations, and financial condition.**

71. The statements referenced in ¶ 70 were materially false and/or misleading because they misrepresented and/or failed to disclose the following adverse facts pertaining to the Company's business and operations which were known to Defendants or recklessly disregarded by them: (i) the USPTO had already issued a notice of Non-Final rejection of the November 2015 SkinTE Patent Application, the Company's leading product; and (ii) the

Company knew there was a substantial likelihood that the Company's engineering platform would never receive a patent.

72. On December 15, 2017, PolarityTE issued a press release "announc[ing] Application of SkinTE on First Patients." The press release stated (emphasis supplied): "About SkinTE™ and FDA Tissue Establishment Registration **SkinTE™ is regulated by the FDA as an HCT/P solely under Section 361 of the Public Health Service Act and 21 CFR 1271."**

73. The statements referenced in ¶ 72 were materially false and/or misleading because they misrepresented and/or failed to disclose that SkinTE was not eligible for regulation solely under Section 361 on the grounds it failed to meet any of the three criteria required to avoid pre-market clearance and approval requirements, which was known to Defendants or recklessly disregarded by them.

74. On January 30, 2018 PolarityTE filed a Form 10-K with the SEC, for fiscal year ended October 31, 2017, signed by Defendants Lough and Stetson (the "2017 10-K"). The 2017 10-K also contained the same Section 302 SOX certifications by Defendants Lough and Stetson referenced in ¶ 61.

75. In the 2017 10-K, the Company discussed intellectual property risks in generic terms, while never disclosing the Non-Final Rejection of the November 2015 SkinTE Patent Application, its leading product (emphasis supplied):

> **We cannot ensure that any of the pending patent applications we acquire, have acquired, or may file will result in issued patents.** Competitors may be able to design around our patents or develop procedures that provide outcomes that are comparable or even superior to ours. . . . **The failure to obtain and maintain patents and/or protect our intellectual property rights could have a material and adverse effect on our business, results of operations, and financial condition.**

76. The statements referenced in ¶ 75 were materially false and/or misleading because they misrepresented and/or failed to disclose the following adverse facts pertaining to the

Company's business and operations which were known to Defendants or recklessly disregarded by them: (i) the USPTO had already issued a notice of Non-Final rejection of the November 2015 SkinTE Patent Application, the Company's leading product; and (ii) the Company knew there was a substantial likelihood that the Company's engineering platform would never receive a patent.

77. In the 2017 10-K, the Company also made the following statements (emphasis supplied):

> **Our first product, SkinTE™, is registered with the United States Food and Drug Administration, or the FDA, pursuant to the regulatory pathway for human cells, tissues, and cellular and tissue-based products (HCT/Ps) regulated solely under Section 361 of the Public Health Service Act, or 361 HCT/Ps, which permits qualifying products to be marketed without first obtaining FDA marketing authorization or approval**.
>
> ***
>
> ***Efficient Regulatory Pathway***. **We believe our products and product candidates, including SkinTE, are appropriately regulated by the FDA as 361 HCT/Ps, which provides us with the potential to register and list products with the FDA, and begin commercializing quickly and efficiently.**
>
> ***
>
> **SkinTE was registered as a 361 HCT/P with the FDA pursuant to Section 361 of the Public Health Service Act and 21 CFR 1271**.

78. The statements referenced in ¶ 77 were materially false and/or misleading because they misrepresented and/or failed to disclose that the SkinTE product was not eligible for regulation solely under Section 361 on the grounds that it failed to meet any of the three criteria required to avoid pre-market clearance and approval requirements, which was known to Defendants or recklessly disregarded by them.

Second Quarter Fiscal Year 2018 (February 1, 2018-April 30, 2018)

79. On February 2, 2018, PolarityTE issued a press release "Provid[ing] Business Updates on Clinical Use of SkinTE: Regeneration of Full-Thickness Skin." The press release

stated (emphasis supplied): "**About SkinTE™ SkinTE is regulated by the FDA as an HCT/P solely under Section 361 of the Public Health Service Act and 21 CFR 1271**."

80. The statements referenced in ¶ 79 were materially false and/or misleading because they misrepresented and/or failed to disclose that the SkinTE product was not eligible for regulation solely under Section 361 on the grounds that it failed to meet any of the three criteria required to avoid pre-market clearance and approval requirements, which was known to Defendants or recklessly disregarded by them.

81. On March 14, 2018, PolarityTE filed a Form S-3 with the SEC, signed by Defendants Lough and Stetson, which stated (emphasis supplied):

> **Our first product, SkinTE™, is registered with the United States Food and Drug Administration ("FDA") pursuant to the regulatory pathway for human cells, tissues, and cellular and tissue-based products (HCT/Ps) regulated solely under Section 361 of the Public Health Service Act ("361 HCT/Ps"), which permits qualifying products to be marketed without first obtaining FDA marketing authorization or approval…"**

82. The statements referenced in ¶ 81 were materially false and/or misleading because they misrepresented and/or failed to disclose that the SkinTE product was not eligible for regulation solely under Section 361 on the grounds that it failed to meet any of the three criteria required to avoid pre-market clearance and approval requirements, which was known to Defendants or recklessly disregarded by them.

83. On March 19, 2018, PolarityTE filed a Form 10-Q with the SEC ("March 19, 2018 10-Q"), for the period ended January 31, 2018, signed by Defendants Lough and Stetson. The March 19, 2018 10-Q also contained the same Section 302 SOX certifications by Defendants Lough and Stetson referenced in ¶ 61. The March 19, 2018 10-Q discussed intellectual property risks in generic terms, while never disclosing the Non-Final Rejection of the November 2015 SkinTE Patent Application, its leading product (emphasis supplied):

> **We cannot ensure that any of the pending patent applications we acquire, have acquired, or may file will result in issued patents.** Competitors may be able to design around our patents or develop procedures that provide outcomes that are comparable or even superior to ours. . . . **The failure to obtain and maintain patents and/or protect our intellectual property rights could have a material and adverse effect on our business, results of operations, and financial condition.**

84. The statements referenced in ¶ 83 were materially false and/or misleading because they misrepresented and/or failed to disclose the following adverse facts pertaining to the Company's business and operations which were known to Defendants or recklessly disregarded by them: (i) the USPTO had already issued a notice of Non-Final rejection of the November 2015 SkinTE Patent Application, the Company's leading product; and (ii) the Company knew there was a substantial likelihood that the Company's engineering platform would never receive a patent.

85. The March 19, 2018 10-Q also made the following statements (emphasis supplied): **"We believe that our current product candidates are appropriately regulated under Section 361 of the Public Health Service Act (so-called '361 HCT/Ps') and that as a result no premarket review or approval by the FDA is required."**

86. The statements referenced in ¶ 85 were materially false and/or misleading because they misrepresented and/or failed to disclose that the SkinTE product was not eligible for regulation solely under Section 361 on the grounds that it failed to meet any of the three criteria required to avoid pre-market clearance and approval requirements, which was known to Defendants or recklessly disregarded by them.

87. On April 11, 2018, PolarityTE issued a press release announcing a stock offering. In connection with the offering, on April 13, 2018, PolarityTE filed a prospectus with the SEC on Form 424B5 ("the April 2018 Form 424B5"), offering 2,031,250 shares of the Company's common stock for total gross proceeds of approximately $30 million.

88. The April 2018 Form 424B5 had generic risk statements regarding potential "developments" concerning "patents" without mentioning the Non-Final Rejection of the November 2015 SkinTE Patent; its leading product (emphasis supplied): "Some of the factors that may cause the market price of our common stock to fluctuate or decrease below the price paid in this offering include: . . .**developments or disputes concerning patents** or other proprietary rights;"

89. The statements referenced in ¶ 88 were materially false and/or misleading because they misrepresented and/or failed to disclose the following adverse facts pertaining to the Company's business and operations which were known to Defendants or recklessly disregarded by them: (i) the Company has no patents; (ii) the USPTO had already issued a notice of Non-Final rejection of the November 2015 SkinTE Patent Application, the Company's leading product; and (iii) the Company knew there was a substantial likelihood that the Company's engineering platform would never receive a patent.

90. The April 2018 Form 424B5 also stated (emphasis supplied):

> **Our first product, SkinTE™, is registered with the United States Food and Drug Administration ("FDA") pursuant to the regulatory pathway for human cells, tissues, and cellular and tissue-based products ("HCT/Ps") regulated solely under Section 361 of the Public Health Service Act ("361 HCT/Ps"), which permits qualifying products to be marketed without first obtaining FDA marketing authorization or approval**…

91. The statements referenced in ¶ 90 were materially false and/or misleading because they misrepresented and/or failed to disclose that the SkinTE product was not eligible for regulation solely under Section 361 on the grounds that it failed to meet any of the three criteria required to avoid pre-market clearance and approval requirements, which was known to Defendants or recklessly disregarded by them.

Third Quarter Fiscal Year 2018 (May 1, 2018-July 31, 2018)

92. On June 4, 2018, the USPTO posted on PolarityTE's Public PAIR the Final Rejection of the November 2015 SkinTE Patent Application. *See* § VI. B. 5. The USPTO determined that "no claim is allowed" because they were "obvious" as defined by 35 U.S.C. 103.

93. On June 4, 2018, the same day USPTO's Final Rejection was posted on the Public PAIR, PolarityTE issued a press release announcing a stock offering. In connection with the offering, on June 7, 2018, PolarityTE filed with the SEC a prospectus on Form 424B5 ("the June 2018 Prospectus"), offering 2,135,550 shares of the Company's common stock priced at $25.50 per share.

94. The June 2018 Prospectus had generic risk statements regarding potential "developments" concerning "patents" without mentioning the Non-Final or Final Rejection of the November 2015 SkinTE Patent, its leading product (emphasis supplied): "Some of the factors that may cause the market price of our common stock to fluctuate or decrease below the price paid in this offering include: . . . **developments or disputes concerning patents** or other proprietary rights;"

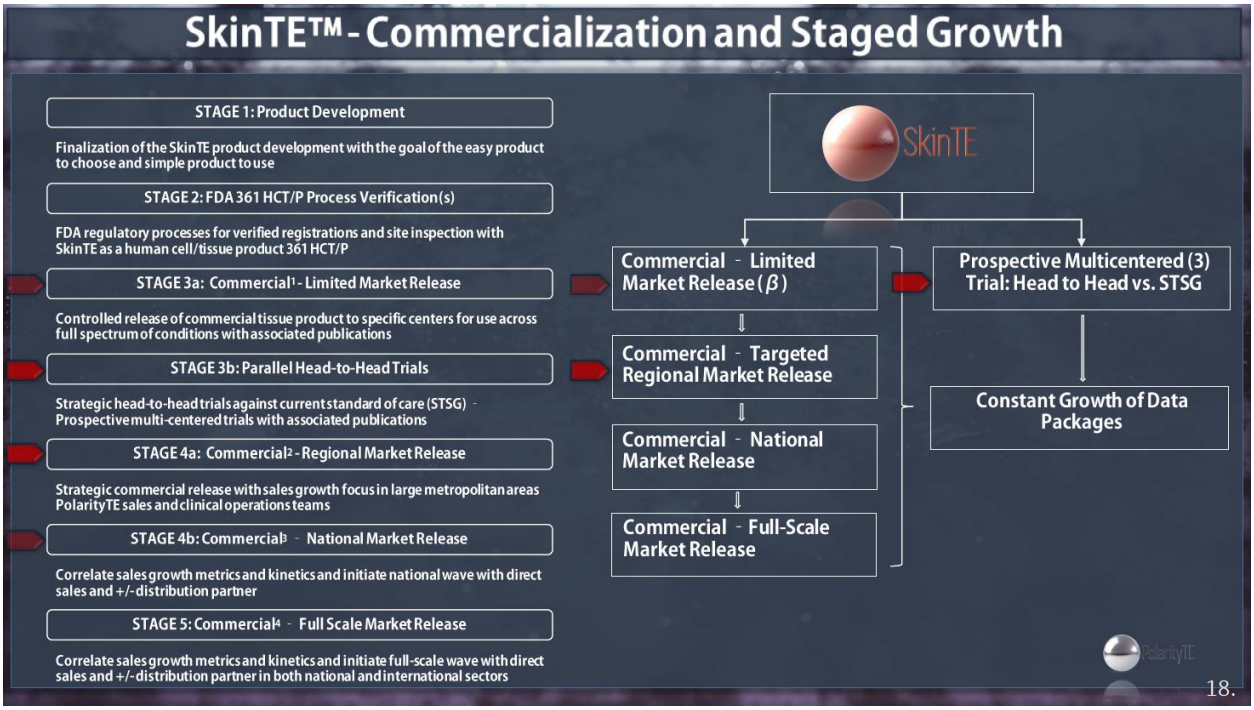
95. The statements referenced in ¶ 94 were materially false and/or misleading because they misrepresented and/or failed to disclose the following adverse facts pertaining to the Company's business and operations which were known to Defendants or recklessly disregarded by them: (i) the Company had no patents; (ii) the USPTO had already issued a notice of Non-Final and Final rejection of the November 2015 SkinTE Patent Application, the Company's leading product; and (iii) the Company knew there was a substantial likelihood that the Company's engineering platform would never receive a patent.

96. The June 2018 Prospectus also stated (emphasis supplied):

> **Our first product, SkinTE™, is registered with the United States Food and Drug Administration ("FDA") pursuant to the regulatory pathway for human cells, tissues, and cellular and tissue-based products (HCT/Ps) regulated solely under Section 361 of the Public Health Service Act ("361 HCT/Ps"), which permits qualifying products to be marketed without first obtaining FDA marketing authorization or approval,** and is commercially available for the repair, reconstruction, replacement and regeneration of skin (i.e., homologous uses) for patients who have suffered from wounds, burns or injuries that require skin coverage over both small and large areas of their body.

97. The statements referenced in ¶ 96 were materially false and/or misleading because they misrepresented and/or failed to disclose that the SkinTE product was not eligible for regulation solely under Section 361 on the grounds that it failed to meet any of the three criteria required to avoid pre-market clearance and approval requirements, which was known to Defendants or recklessly disregarded by them.

98. On June 4, 2018, PolarityTE filed a Form 8-K with the SEC, signed by Defendant Stetson, attaching as Exhibit No. 99.1, a PolarityTE Business Presentation, dated June 2018. Slide 18 of the presentation had the heading, "SkinTE – Commercialization and Staged Growth." Thereunder, the presentation had certain subheadings purporting to explain the product marketing of the SkinTE. One of the subheadings stated (emphasis supplied): **"STAGE 2: FDA 361 HCT/P Process Verification(s). FDA regulatory processes for verified registrations and site inspection with SkinTE as human cell/tissue product 361 HCT/P."**



99. The statement referenced in ¶ 98 was materially false and/or misleading because they misrepresented and/or failed to disclose the following adverse facts pertaining to the Company's business and operations which were known to Defendants or recklessly disregarded by them: (i) the SkinTE product was not eligible for regulation solely under Section 361 on the grounds that it failed to meet any of the three criteria required to avoid pre-market clearance and approval requirements; and (ii) misrepresented that SkinTE's eligibility for regulation solely under Section 361 had been or would be verified by the FDA.

100. On June 14, 2018, PolarityTE filed a Form 10-Q with the SEC, for the period ended April 30, 2018, signed by Defendants Lough and Stetson (the "June 14, 10-Q"). The June 14, 2018 10-Q contained the same Section 302 SOX certifications by Defendants Lough and Stetson referenced in ¶ 61. The Company discussed in general terms the potential risks to its ability to raise capital and conduct operations, if it was unable to obtain patents, without

disclosing the Final Rejection of the November 2015 SkinTE Patent Application, its leading product (emphasis supplied):

> In order to grow and expand our business, and to introduce our new product candidates into the marketplace, we will need to raise a significant amount of additional funds. We will also need significant additional funds or a collaborative partner, or both, to finance the research and development activities. Accordingly, we are continuing to pursue additional sources of financing. **Our future capital requirements will depend on numerous factors, including:…our ability to obtain valid and enforceable patents.**

101. The statement referenced in ¶ 100 was materially false and/or misleading because they misrepresented and/or failed to disclose the following adverse facts pertaining to the Company's business and operations which were known to Defendants or recklessly disregarded by them: (i) that the USPTO had posted a Final Rejection of the November 2015 SkinTE Patent Application, its lead product, on June 4, 2018; and (ii) the Company knew there was a substantial likelihood that the Company's engineering platform would never receive a patent.

102. On June 27, 2018, PolarityTE issued a press release to "[p]rovide Update on Key Opinion Leader Event and Addresses Misleading Report." With respect to SkinTE, the press release stated (emphasis added): "**About SkinTE™ SkinTE is regulated by the FDA as an HCT/P solely under Section 361 of the Public Health Service Act and 21 CFR 1271.**"

103. The statements referenced in ¶ 102 were materially false and/or misleading because they misrepresented and/or failed to disclose that the SkinTE product was not eligible for regulation solely under Section 361 on the grounds that it failed to meet any of the three criteria required to avoid pre-market clearance and approval requirements, which was known to Defendants or recklessly disregarded by them.

104. On September 12, 2018, PolarityTE conducted an earnings conference call with analysts to discuss PolarityTE's 3Q 2018 results (the "September 12, 2018 Conference Call").

Defendant Lough made the following statement regarding PolarityTE's manufacturing capabilities:

> **We've also designed and built our first scalable biomedical manufacturing facility. In the first half of 2018, we moved our headquarters to a new 200,000-square-foot facility in Salt Lake City and completed the construction and validation of our first series of high-throughput manufacturing suites, which were designed not just to support the manufacturing of SkinTE, but the other core TE technologies and pipeline products.**

105. The statements referenced in ¶ 104 were materially false and/or misleading because while touting the Company's manufacturing capabilities, the Company failed to disclose that on July 13, 2018, PolarityTE received a Form 483 denoting eight violations of FDA regulations which could threaten the SkinTE launch. Such adverse facts, pertaining to the Company's business and operations, were known to Defendants or recklessly disregarded by them.

106. On September 13, 2018, Defendant Lough spoke at the Morgan Stanley Healthcare Conference about PolarityTE's manufacturing capabilities, stating:

> PETER HARRISON: Any questions from the audience? I guess maybe talk a little bit about your manufacturing process. I mean, I know you've talked about manufacturing nodes throughout the country, the timing of that, as you think about launching more broadly outside of the 2 regions you're currently in.
>
> DENVER M. LOUGH: Yes, absolutely. . . . We designed, developed and rolled out our manufacturing process in a manner, and respecting the fact that we wanted to maintain a lower COGS element and be able to get that price -- that product back to patients that were in need of it very quickly. **Our manufacturing product -- process basically surrounds something what we the call [C-pack] units, controlled production, environmental columns, which are very large clean rooms essentially about the size of something like this, which then contain essentially smaller clean rooms or [LFGIs], laminar flow glow lights that are boxes that are in them, which allow us to turnover products much more quickly and efficiently, and sort of creating a little bit more of, I would call it, an assembly line mechanism in order for us to maintain the absolute utmost aseptic technique, the best quality checks and assessment possible for it,** but to be able to move the product through more quickly, not culture and expand it in any form, during the manufacturing process and, in fact, allow it to be expanded and cultured on the patient themselves.

107. The statements referenced in ¶ 106 were materially false and/or misleading because while touting the Company's manufacturing capabilities, the Company failed to disclose that on July 13, 2018, PolarityTE received a Form 483 denoting eight violations of FDA regulations which could threaten the SkinTE launch. Such adverse facts, pertaining to the Company's business and operations, were known to Defendants or recklessly disregarded by them.

108. On January 14, 2019, Polarity filed a Form 10-K with the SEC for the fiscal year ended October 31, 2018, signed by Defendant Lough (the "2018 10-K"). The 2018 10-K contained the same SOX certification by Defendant Lough referenced in ¶ 61.

109. In the 2018 10-K, the Company discussed in generic terms the potential adverse effect that investigatory and regulatory risks could have on its common stock price, while never disclosing that in October 2018 the SEC had sent PolarityTE document requests and inquiries relating to subjects addressed in the short seller reports published by *Citron Research* and others (emphasis supplied):

> Our stock price has been highly volatile during the fiscal year ended October 31, 2018, with closing stock prices ranging from a high of $38.97 per share to a low of $12.11 per share…**The market price for our common stock may be influenced by many factors, including:…**
>
> - **announcement of investigations or regulatory scrutiny of our operations or lawsuits filed against us;**
>
> ***
>
> **In the ordinary course of business, we may become involved in lawsuits, claims, investigations, proceedings, and threats of litigation relating to intellectual property, commercial arrangements, regulatory compliance, and other matters. Except as noted above, at October 31, 2018, we were not party to any legal or arbitration proceedings that may have significant effects on our financial position or results of operations. No governmental proceedings are pending or, to our knowledge, contemplated against us.** We are not a party to any material proceedings in which any director, member of senior management or affiliate of ours is either a party adverse to us or our subsidiaries or has a material interest adverse to us or our subsidiaries.

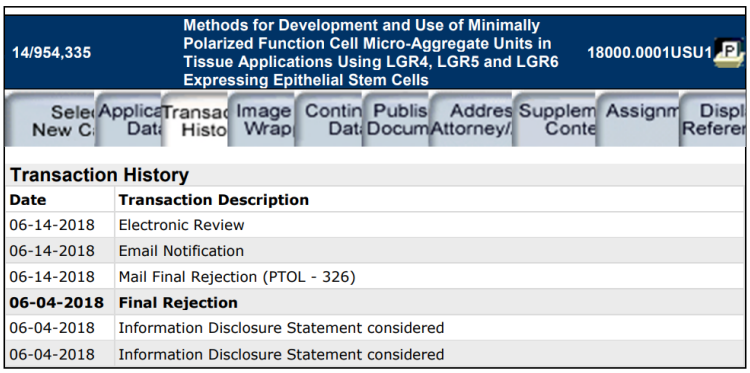
110. The statements referenced in ¶ 109 were materially false and/or misleading because they misrepresented and/or failed to disclose that the Company had already been subjected to regulatory scrutiny by the SEC of its operations which could adversely affect its stock price, which was known to Defendants or recklessly disregarded by them. Defendants also likely knew that governmental proceedings were contemplated against the Company.

V. THE TRUTH BEGINS TO EMERGE

111. On October 25, 2017, *Seeking Alpha* published an article by White Diamond Research titled, "PolarityTE: A Comprehensive Look At The Bull Vs. Bear Cases, exposing the fact that the SkinTE was not patented technology. The article was published a day after Defendant Lough's interview with FOX business, *supra* at ¶¶ 7, 68, where he falsely stated that the SkinTE process was patented. As discussed, *supra* ¶¶ 49-110 and further discussed *infra* ¶¶ 190-211, from before the start the Class Period up until Defendant Lough's FOX interview on October 24, 2017, the Company issued contradictory and misleading statements respecting the November 2015 SkinTE Patent Application. At times, Defendants made statements stating that the Company had a "patented technology" while at others stating that it had a "patent application". The October 25, 2017 *Seeking Alpha* article exposed for the first time PolarityTE's flip flopping (emphasis in original): "**PolarityTE's SkinTE Product Is 'Patent Pending'** In the company's IR deck, on page 6 it claims that Dr. Denver Lough is the inventor/innovator behind patented PolarityTE platform. However, in the company's latest 10-Q, it clearly indicates that the company's asset is a patent *application* that has not yet been granted by the USPTO."

112. Following the disclosures in the *Seeking Alpha* article, PolarityTE's share price fell $0.98, or $3.94%, over a two-day decline, to close at $23.92 on October 26, 2017.

113. On June 25, 2018, *Citron Research* published a report titled, "Citron Exposes History of FRAUD Behind PolarityTE…" exposing the Defendants' failure to disclose the Company's March 31, 2017 notice of Non-Final Rejection of the November 2015 SkinTE Patent Application, and also highlighted the USPTO's Final Rejection of the 2015 SkinTE Patent Application on June 4, 2018:



14/954,335	Methods for Development and Use of Minimally Polarized Function Cell Micro-Aggregate Units in Tissue Applications Using LGR4, LGR5 and LGR6 Expressing Epithelial Stem Cells	18000.0001USU1

Sele New C | Applica Data | Transac Histo | Image Wrap | Contin Data | Publis Docum | Addres Attorney/ | Supplem Conte | Assignm | Displ Referer

Transaction History

Date	Transaction Description
06-14-2018	Electronic Review
06-14-2018	Email Notification
06-14-2018	Mail Final Rejection (PTOL - 326)
06-04-2018	**Final Rejection**
06-04-2018	Information Disclosure Statement considered
06-04-2018	Information Disclosure Statement considered

114. Following the disclosures in the *Citron Research* report, PolarityTE's share price fell $12.32, or 31.81%, over a two-day decline, to close at $26.40 on June 26, 2018.

115. On June 27, 2018, PolarityTE issued a press release to "[p]rovide Update on Key Opinion Leader Event and Addresses Misleading Report." With respect to the *Citron Research* published report, PolarityTE stated:

> Regarding online statements about a "non-final rejection" and a "final rejection" notice from the USPTO, the Company notes that such statements refer to the receipt of office actions from the USPTO…The Company is actively pursuing a variety of claims within multiple published non-provisional patent applications in the U.S…It is common for a first office action to be referred to as a "non-final rejection," and for a second office action to be referred to as a "final rejection."

116. Following the disclosures and confirmation by PolarityTE that it had received Non-Final and Final Rejections regarding the November 2015 SkinTE Patent Application, PolarityTE's share price fell another $3.35, or 12.68%, to close at $23.06, on June 27, 2018.

117. On July 20, 2018, *Seeking Alpha* published an article by *Research Noir* titled, "Citron Just Scratched The Surface: Material Omissions and False Claims From PolarityTE,"

exposing the fact that the SkinTE product did not meet the requirements for regulation under Section 361 because the product did not meet the "minimally manipulated" and "not combined with another article" prongs necessary for regulation *solely* under Section 361.

118. According to the *Seeking Alpha* article, a review of the November 2015 SkinTE Patent Application; other relevant patent applications related to the November 2015 SkinTE Patent Application; Lough's papers describing the data and science behind the product; PolarityTE's SEC filings and presentations; and FDA guidance demonstrated that the SkinTE product did not meet, and could not possibly have met, the requirements for regulation *solely* under Section 361. The author observed that the SkinTE product: (1) is not minimally manipulated and (2) its manufacture entailed a combination with other products. Defendants, having access to all the relevant information, could not have reasonably concluded that SkinTE could meet the requirements for regulation solely under Section 361.

119. On July 23, 2018, *Ozgur Ogut* published an article titled, "SkinTE and the FDA's 361 Pathway" further exposing the fact that the SkinTE product did not meet regulation under Section 361, because the product – in addition to not meeting the "minimally manipulated" and "not combined with another article" prongs – also did not meet the "homologous use" prong.

120. Following disclosures in the *Seeking Alpha* and the *Ozgur Ogut* articles, PolarityTE's share price fell $2.54, or 12.41%, over the following two trading sessions, to close at $17.93 on July 23, 2018.

121. On September 7, 2018, the SEC filed a complaint in the U.S. District Court for the Southern District of New York (*SEC v. Honig et al.*, No. 1:18-cv-01875 (S.D.N.Y. 2018)) against a nefarious group of stock promoters that allegedly included Defendant Stetson, the Company's former Chief Financial Officer and Chief Investment Officer, along with Honig, and Brauser. The complaint alleged that the group manipulated the price of securities of three public

companies.

122. On this news, PolarityTE's share price fell $3.92, or 16.03%, to close at $20.54 on September 7, 2018.

123. On September 25, 2018, *The Capitol Forum* published an article with the headline, "PolarityTE: FDA Form 483 Raises Issues with SkinTE Processing and Operations." The content available to the non-subscribing public stated: "The FDA has identified issues at PolarityTE's (PTE) SkinTE facility that may violate the Food Drug and Cosmetic Act, according to a Form 483 that was issued to PolarityTE after the FDA conducted an inspection of the facility between July 9 and 13, 2018."

124. Following this news headline from *The Capitol Forum*, PolarityTE's share price fell $2.90, or 12.87%, over a two-day decline, to close at $18.95 on September 26, 2018.

125. On October 18, 2018, *Citron Research* published a report titled: "PolarityTE: This Game Is Over! Price Target - $2 The FDA Has Spoken!" In addition to reporting that PolarityTE received a Form 483, *Citron Research* included a link to the actual Form 483 which detailed the eight FDA observations of violations of FDA regulations.

126. Following the report on October 18, PolarityTE's share price fell $2.49, or 17.05%, to close at $12.11 on October 18, 2018. The price impact of the corrective disclosure was lessened by PolarityTE's response in a press release denying the conclusions *Citron Research* reached.

127. On March 18, 2019, PolarityTE filed a Form 10-KT, which disclosed for the first time that the Company was being investigated for securities fraud, stating:

> In October 2018, we received a document request and inquiries from the SEC relating to subjects addressed in the short seller reports and cooperated fully by providing the SEC with all information relevant to their requests. On March 1, 2019, we received a subpoena from the SEC requesting additional documents related to, among other things, (i) communications and agreements between us and, among others, John Stetson, Barry Honig and Michael Brauser, (ii) the

> transaction pursuant to which Majesco Entertainment Company acquired PolarityTE NV and our current regenerative medicine business, (iii) the performance of and communications with regulators regarding SkinTE, our lead product, and (iv) any promotion of the Company or its securities. On March 4, 2019, we obtained from the SEC a copy of the formal order of investigation of the Company and its affiliates with respect to possible violations of the federal securities laws, including, among other things, the anti-fraud provisions of the Securities Act and the Exchange Act with respect to the Company's public disclosures, the beneficial ownership reporting provisions of the Exchange Act and the anti-price manipulation provisions of the Exchange Act. We intend to fully cooperate with the SEC regarding their March 2019 subpoena and this ongoing investigation.

128. Following the disclosure in March 18, 2019 10-KT, PolarityTE's stock price fell $3.39, or 21.91%, over a three-day decline, to close at $12.08, on March 20, 2019.

129. As a result of Defendants' wrongful acts and omissions, and the precipitous decline in the market value of the Company's common shares, Plaintiff and other Class members have suffered significant losses and damages.

VI. ADDITIONAL SCIENTER ALLEGATIONS

A. PolarityTE Was Designed As A Vehicle For A Pump And Dump Securities Fraud

1. The SEC Charges A Cast of Characters Involved In The PolarityTE-Majesco Reverse-Merger With Orchestrating Pump And Dump Schemes In Three Unrelated Companies

130. On September 7, 2018, the SEC filed a complaint (the "SEC Complaint") charging a group of individuals and associated entities with violations of federal securities laws for their participation in a long-running fraudulent scheme involving three entities. On March 8, 2019, the SEC filed an amended complaint (the "SEC Amended Complaint", together with the "SEC Complaint", are hereinafter the "SEC Complaints"). According to the SEC complaints, from 2013 to 2018, a group of "prolific fraudsters" manipulated the share price of the stock of three companies in classic pump-and-dump schemes.

131. Honig was the "primary strategist" of the schemes that were "orchestrated" with

Defendant Stetson and Messrs. Brauser, Phillip Frost ("Frost"), and Mark Groussman ("Groussman") along with various others ("Honig and his associates") to acquire large quantities of the issuer's stock at steep discounts, either via reverse mergers or participating in financings on terms highly unfavorable to the company at issue.

132. After the acquisition, Honig, and some combination his associates, either explicitly or tacitly agreed to buy, hold or sell their shares in coordination, knowing that they would orchestrate a pump and dump of the stock in the near future which would allow them to profit. Once the group had acquired substantial ownership of the issuer, they acted as an undisclosed control group, directed the management which included orchestrating transactions designed to create market interest, and arranged for the promotion of the stock by directing favorable and misleading articles about the company intended to inflate the stock price. The SEC Amended Complaint went into great detail regarding Defendant Stetson's role in coordinating the posting of favorable and misleading articles. The SEC Amended Complaint also noted that Honig and his associates, either individually or through their entities, invested alongside one another in at least 19 issuers from 2011 to the present, engaging in the same fraudulent practices.

133. In connection with the schemes, Honig and his associates violated beneficial ownership reporting requirements of federal securities laws by failing to disclose their group beneficial ownerships and the fact that as a group, they intended to control the issuers. All told, in connection with the fraudulent actions involving the three entities in the SEC Complaints, the schemes profited Honig and his associates to the tune of more than $27 million and left public investors in these companies holding virtually worthless stock. **A review of PolarityTE's formation and background demonstrates that Honig and his associates sought to structure PolarityTE in the same fashion as their other companies discussed in the SEC Complaints.**

2. Honig And His Associates Invest In Majesco And Orchestrate Stock Maneuvers To Profit From The Failing Company

134. PolarityTE is the latest iteration of a public company that has managed to morph into six seemly unrelated different companies: SMD Group, Inc., CDBeat.com,Inc., Spinrocker.com, Inc.; ConnectivCorp; and Majesco.

135. Honig, Brauser, Groussman and Frost became involved in Majesco when they acquired, in concert, more than 80% of the common stock of preferred stock (taking into account subsequent reverse splits and warrants) issued by Majesco in December 17, 2014 and May 15, 2015 private placements, which amounted to $11 million. Majesco was a developer, publisher, and distributor of entertainment for video game consoles.

136. On October 2, 2015, Majesco announced that on September 25, 2015 the board of directors had increased its size and appointed Honig and Brauser as new members. The board of directors also announced that it had appointed Honig to serve as Chairman and Chief Executive Officer, and appointed Defendant Stetson to serve as Chief Financial Officer, Executive Vice President and Secretary. Brauser was appointed as Co-Chairman of the Board of Directors.

137. In connection with the October 5, 2015 announcement, Honig stated, "With Majesco's further enhanced strong balance sheet and reduced cost structure, I believe now is an opportune time to lead the Company with total focus on creating value for shareholders."

138. Nevertheless, according to Majesco's Form 10-K for the fiscal year ended October 31, 2015, which was filed on January 29, 2016, its revenues had fallen by 80%. In its filing, Majesco further disclosed, "We are currently not developing any significant new packaged games for release in fiscal 2016 and our objectives include…the potential merger with or acquisition of a new business in a similar or different industry from our current and historical operations, although no business or industry has been determined to be an attractive candidate."

139. The January 29, 2016 10-K's risk disclosures stated that, among others, "Our

review of our strategic alternatives may result in a complete transformation of our Company . . . ; Our financial resources are limited and we will need to raise additional capital in the future to continue our business; We have experienced recent net losses and we may incur future net losses, which may cause a decrease in our stock price."

140. Yet despite this grim financial outlook, on January 6, 2016 the board of directors authorized a special dividend. In the announcement, Honing stated, "This special dividend is another step in returning value to shareholders. We will continue to explore options for delivering value with our low overhead and cash position."

141. A January 5, 2016 Form 8-K filing shows that Majesco paid $10 million in special dividends to holders of its common stock and preferred stock; $6 million of that going to holders of preferred stock. The cash was distributed in January 2015. **Therefore, Honig, Frost, Brauser and Grossman received back over half of their original December 2014 and May 2015 investments in Majeco stock and got to keep their shares.** They also held most of that stock when Majesco agreed to acquire PolarityTE.

142. All the while, Majesco continued to falter as a business as it reported $1 million in revenue for the first half of 2016, down from $5.2 million in the same period of 2015; and it reported net losses of $7.7 million, up from $5 million in the same period of 2015. Through the rest of 2016, Majesco engaged in placements which included warrants and 1-6 reverse stock splits which greatly benefitted Honig, Frost, Brauser and Groussman. A Form S-3 filed by PolarityTE with the SEC on August 3, 2016 shows that Honig and his associates controlled 3.7 million shares in the month leading up to the PolarityTE deal; almost two-thirds of the company's stock on a fully diluted basis. Majesco continued to falter, with just $315,000 in revenue for the three months that ended in July 31, 2016 down from $1.1 million a year earlier, yet Honig and his associates continued to profit.

3. The Majesco-PolarityTE Merger

143. On December 7, 2016, Majesco filed a Form 8-K disclosing that on December 1, 2016 it had entered into an Agreement and Plan of Reorganization with Majesco Acquisition Corp., a Nevada corporation and wholly-owned subsidiary of Majesco, and PolarityTE, with Defendant Lough the owner of 100% of the issued and outstanding shares of capital stock.

144. On December 8, 2016, Majesco appointed Defendant Lough as Chief Executive Officer and Chairman of the Board, Swanson as Chief Operating Officer and Director and Defendant Stetson as Executive Vice President. Defendant Lough thanked Honig and Frost "for their confidence" in them.

145. The Agreement took the form of a reverse merger – much like the other companies that preceded PolarityTE – which involved the acquisition of a public company (Majesco) by a private company (PolarityTE) so that the private company could bypass the lengthy and complex process of going public. Whereas Majesco, in its latest iteration, was by all measures a 31-year-old failing company focused on video game publishing, PolarityTE described itself as a company "revolutionizing regenerative medicine and inducing a paradigm shift" through an "innovative platform technology."

146. Typically, when a reverse merger entails a company becoming publicly-traded on the NASDAQ, there is a concrete basis and understanding as to what is behind the potential value generation of the company that has bypassed the complex process of going public. Generally, this concrete basis comes in the form of physical assets or a strong intellectual property portfolio. Such was not the case with PolarityTE, although as described herein, PolarityTE's various false and misleading statements obfuscated this fact.

147. As Defendant Lough described in correspondence with the SEC on February 22, 2017, his November 2015 SkinTE Patent Application was the key asset exchanged through the

reverse merger (emphasis supplied): "There was never any intent to acquire an ongoing business and no ongoing business was acquired. ***The asset is preserved in a stand-alone entity merely as a vehicle to provide the Company a seamless means to acquire the asset (a patent application)*** without undue cost, expense and time."

4. The Involvement Of Frost, Honig And Stetson In PolarityTE

148. By the Defendant Lough and Swanson's own admissions, there was no meaningful due diligence conducted between PolarityTE and Majesco. Defendant Lough and Swanson were plastic surgery residents at Johns Hopkins University Hospital when they decided to leave their respective residencies to form PolarityTE.

149. Defendant Lough alleges to have met with various venture capitalists, and to have received term sheet offers, but resisted from entering into any agreement because the venture capitalists wanted control, the majority of equity and were unwilling to put up the financing that Defendant Lough felt was needed to successfully launch the venture. Swanson decided to call Defendant Stetson, an old friend from college, to help him fine-tune their pitch. Defendant Stetson told Swanson that he worked closely with Frost and he thought that Frost would be interested in hearing their pitch.

150. By Defendant Lough's own telling, "Frost and Honig ***dropped a term sheet on us 24 hours after initiating discussions*** — a welcomed pace after enduring multiple rounds of VC due diligence that takes 4-5 months before anyone puts numbers in writing. ***Because of their vast experience in biotech, they quickly understood the potential value of our technology****."*

151. Aside from the equity and control benefits that the deal structure provided, when asked what was so attractive about this structure, Swanson said, "This deal immediately allowed us to put our money where our mouth was." He added, "***After pursuing multiple deal structures with private investors, debating our valuation became tiring, which in the private markets in a***

pre-revenue pre-clinical biotech company is almost entirely imaginary." Of the last 50 biotech startups, only about 14% launched without funding from venture capital firms, and PolarityTE was one of only four life science firms that went public immediately without an Initial Public Offering.

152. While the public merger model used by Honig and his associates lowers the cost of capital for biotech founders and inventors, it is also very profitable for early investors like Frost and Honig. Based upon analysis of five other public reverse merger deals they have executed within the biotech industry since 2014, their average annual return is more than 175%.

5. Honig And Frost Dealings Regarding PolarityTE Stock Mirror The Schemes Outlined In the SEC Complaint And Are Indicative Of A Classic Pump And Dump Scheme

153. By mid-2015, Honig, Brauser, Frost and Groussman owned more than 20% of Majesco's outstanding common shares; this excludes millions of additional shares issuable upon conversion of preferred stock held. Honig, Brauser and Frost were the biggest holders of Majesco preferred stock prior to the Merger. They ranked second third and fourth after the Merger; with Groussman coming in at fifth.

154. In March 2017, Honig filed an amended Form 13D which listed his holdings at 10.7% of PolarityTE's outstanding shares.

155. On April 7, 2017, PolarityTE announced the Merger through which the Company purchased Defendant Lough's November 2015 SkinTE Patent Application in exchange for over $104 million of PolarityTE stock. In connection with the closing of the Merger, on April 5, 2017, the Company issued Defendant Lough 7,050 shares of Series E Convertible Preferred Stock (the "Series E Shares") which are convertible into an aggregate of 7,050,000 shares of the Company's common stock or 40.95% of the Company's then-issued and outstanding common stock on a fully diluted basis.

156. In a Form 8-K filed on April 7, 2017 announcing the Merger, PolarityTE stated (emphasis supplied): "As a result of the Merger Polarityte NV became a wholly owned subsidiary of the Company. ***Polarity[te] NV is the owner of a novel regenerative medicine and tissue engineering platform developed and patented by Dr. Lough***."

157. On June 9, 2017, PolarityTE filed a Form 10-Q Report with the SEC for the period ended April 30, 2017 stating that holders of its Series A, B, C and D preferred stock converted portions of each series, receiving 971,860 common shares. Meanwhile, PolarityTE stock kept climbing and reached $30 per share on June 26, 2017.

158. On July 10, 2017 the Company filed a mixed shelf registration statement for the offering of up to $100 million worth of securities in the form of common stock, preferred stock, warrants, or a combination of these from time to time, in one or more transactions.

159. However, the stock did not rally for long, as it closed at a little under $20 on August 1, 2017. It was then, on August 8, 2017, that an article written by board member Jeff Dyer was published by Forbes titled "PolarityTE: Will This Biotech Be the Next Amazon or Tesla?" As the title indicates, Dyer chronicled the Company as the next breakthrough in the biotechnology field, attracting the interest and involvement of one the world's best biotech investors:

> PolarityTE's technology — if it works — will be extremely disruptive to incumbents . . . Despite the promise of PolarityTE's technology, Lough and Swanson would likely never have resigned from Hopkins to pursue the venture without an innovative financing model . . . Enter billionaire investor Philip Frost and his investment team. In the biotech sector, and especially in small cap ventures, there is no bigger name than Dr. Philip Frost. Across a career spanning over 40 years, Frost has built a net worth over 4 billion dollars, the vast majority of which derives from founding, buying, selling, and investing in biotechnology companies.

160. Although the article disclosed that Dyer was a board member, what was not disclosed was that the Company had granted him options to buy 141,000 shares at an exercise

price of $3.12 a share, and that he stood to profit from any increase in the stock. The article worked – the stock price rose more than 25% in the week that followed and on the last day of August, it reached a new high of $32.63 while closing at $29.09. Unsurprisingly, Dyer filed an S-8 on August 17, 2017 with the SEC to sell 93% of his holdings in PolarityTE. Dyer had known beforehand from communications with his editor at *Forbes* that the article would be published in August, and he used this knowledge to inflate the stock price and turn a huge profit for himself.

161. The article piqued the interest of the SEC, which questioned whether it constituted "gun jumping" since the company had a pending registration. While PolarityTE acknowledged in a letter to the SEC that Dyer had exchanged multiple drafts of the article with Defendant Lough and Swanson, the Company maintained that the piece was similar to others that had been published about the Company in the ordinary course of business. It is worth noting that the inquiry was handled by-then PolarityTE's attorney (and previously Majesco's attorney) Harvey J. Kesner. Kesner retired and left his firm abruptly after the SEC Complaint was filed which featured various companies (linked to Honig) which he represented as counsel.

162. Right after the publishing of the article, between September and mid-December 2017, PolarityTE's definitive 2017 proxy filing showed a decrease of 609,000 shares listed for Honig. Even after these sales, Honig remained PolarityTE's second biggest shareholder and a March 2018 SEC filing showed he still had 1.75 million shares.

163. On September 21, 2017, PolarityTE announced the closing of $17.75 million of Series F Convertible Preferred Stock. The preferred stock is convertible into the Company's common stock at a conversion price of $27.50 per share and the investor shall receive one half warrant exercisable at $30.00 per share. On September 21, 2017 the Company's stock was trading at $26.50 per share.

164. The September 21, 2017 announcement called the preferred stock "Above Market" since the conversion price on the preferred stock and exercise price on the warrants was above the market price at $27.50 and $30 respectively. This made it seem like the preferreds were an underpinning of value at $27. However, the opposite is actually true. The preferreds were full ratchet, meaning if the Company sells stock for a lower price in the future, the conversion price of the preferreds changes to that price and the warrant exercise price changes to 110% of that price. Therefore, with all of these price protection terms, the buyers of the preferreds and warrants had almost no risk, compared to the risk of investors who buy the stock on the open market.

165. On April 17, 2018 PolarityTE issued a press release announcing the close of its public offering of 2,031,250 shares of common stock, plus an additional 304,687 shares sold upon full exercise of the underwriter's option. Net proceeds to the Company from the offering were approximately $34.2 million.

166. As discussed in more detail *infra* ¶¶ 205-211, PolarityTE's leading product received a Final Rejection of its filed patent application on June 4, 2018 – the same day that PolarityTE announced yet another public offering. On June 5, 2018, PolarityTE announced a pricing at $55 million which closed on June 7, 2018, but made no mention of the Final Rejection. Just a week earlier, on May 29, 2018, PolarityTE filed an S-8 with the SEC, covering the sale of 7.3 million shares, worth upwards $190 million held by current and former officers, directors and insiders including Honig, Stetson and Brauser. Also, as discussed in more detail *infra* ¶¶ 205-211, PolarityTE did not disclose the Final Rejection of its filed patent application when it found out, in the middle of the public offering. PolarityTE stock hit a high of $41.22 on June 21 (closing at $38.97), and SEC filings show that Honig and Frost sold $19-$23 million worth of stock; some between June and August, when the stock was taking off and some in the fall and

winter. All told, Honig and Frost sold more than $20 million of their PolarityTE stock between February 2017 and February 2018 – most coming in the second half of 2017. Honig failed to report sales as required under Regulation 13D; one of the same strategies detailed by the SEC Complaints as used by Honig and his associates to conceal their acting in concert. In fact, Honig ended up switching his status from a 13D filer to 13G filer – contending that because he would not hold shares for control, he did not have to report them. However, PolarityTE's proxy filing of August 2018 showed that Honig, Frost, Groussman, Stetson and Brauser still controlled 4.5 million shares.

167. Furthermore, supposed independent directors of PolarityTE had undisclosed ties to Honig. For example, PolarityTE board members Steve Gorlin and Jon Mogford, were board members at Medovex Corp. Gorlin was the founder of Medovex Corp – a medical products company to which Honig, Stetson, and Groussman provided funding.

168. On September 7, 2018, after the SEC Complaint was filed against Honig and his associates (including Defendant Stetson), PolarityTE issued a press release announcing that the Company had terminated Stetson and added, "None of the other defendants listed in the complaint filed by the SEC has any recent management, employment, or consulting relationship with the Company, nor will there be any such relationship in the future." Defendants have not addressed the various stock maneuvers by Honig and his associates in PolarityTE and Majesco and have claimed no knowledge of the activities at issue in the SEC Complaints.

169. In an SEC filing on October 2018, Defendant Stetson reported that he had sold $5.5 million worth of PolarityTE stock. SEC filings also show that Groussman sold 121,000 shares in the past year. All told, Stetson Honig, Groussman and Frost appear to have sold over $30 million in PolarityTE stock over the last year. Meanwhile, PolarityTE's 4Q and Fiscal Year 2018 results show, that in the past two fiscal years, the Company reported net revenues

amounting to $1.563 million while reporting losses amounting to over $200 million. While Frost reported in an SEC filing on January 2019 that he no longer owns stock in PolarityTE, SEC filings show that Honig and Brauser still hold 7% each of the stock outstanding which is more than that held by Swanson (around 4%). Frost settled with the SEC in December 2018, and Grossman settled in February of 2019.

6. The SEC launches An Investigation Into PolarityTE

170. In October 2018, PolarityTE received a document request and inquiries from the SEC relating to subjects addressed in the short seller reports published by *Citron Research* and others.

171. On March 1, 2019, Polarity received a subpoena from the SEC requesting additional documents related to, among other things, "(i) communications and agreements between us and, among others, Stetson, Honig and Brauser, (ii) the transaction pursuant to which Majesco Entertainment Company acquired PolarityTE NV and [PolarityTE's] current regenerative medicine business, (iii) the performance of and communications with regulators regarding SkinTE, our lead product, and (iv) any promotion of the Company or its securities."

172. On March 4, 2019, PolarityTE obtained from the SEC a copy of the formal order of investigation of the Company and its affiliates concerning possible violations of the federal securities laws, including, among other things, the anti-fraud provisions of the Securities Act and the Exchange Act with respect to the Company's public disclosures, the beneficial ownership reporting provisions of the Exchange Act and the anti-price manipulation provisions of the Exchange Act.

173. On March 8, 2019, the SEC amended its original complaint as discussed *supra* at ¶¶ 130-133, to allege that the defendants violated the anti-fraud and other provisions of the Securities Act, the Exchange Act and SEC rules promulgated thereunder by writing, or causing

to be written, false or misleading promotional articles, engaging in a variety of other manipulative trading practices as well as filing false reports of their beneficial ownership or failure to file reports of their beneficial ownership when required to do so.

174. On March 15, 2019, PolarityTE filed a Form 10-K with the SEC, which was required because PolarityTE changed the end of its fiscal year to December 31. In the March 15, 2019 filing, PolarityTE revealed that the Company was under investigation by the SEC in connection with possible violations of the federal securities laws, including, among other things, the anti-fraud provisions of the Securities Act and the Exchange Act with respect to the Company's public disclosures, the beneficial ownership reporting provisions of the Exchange Act and the anti-price manipulation provisions of the Exchange Act.

175. At the time of this filing, the SEC investigation remains ongoing.

B. Defendants Knew The SkinTE Patent Application Received Non-Final And Final Rejection From The FDA But Failed To Disclose The Information

176. On March 31, 2017, the USPTO posted its non-final rejection of PolarityTE's November 2015 SkinTE Patent Application to a website available to Defendants.

177. Defendants thus either knew, or recklessly disregarded, the fact that PolarityTE's patent application had been preliminarily, and then finally, rejected when making false statements of fact to investors.

1. How The USPTO Determines Patentability

178. The USPTO is an agency of the U.S. Department of Commerce charged with the role of granting patents for the protection of inventions and to register trademarks.

179. An examiner of the USPTO will review the contents of a patent application to determine if the application meets the requirements of 35 U.S.C. § 111(a) and § 112(a), a written specification containing a description of the invention and particularly pointing out and distinctly claiming the subject matter which the inventor regards as the invention.

180. An examiner may reject the patent application if it fails to meet the "obviousness" test of 35 U.S.C. § 103 – if the differences between the claimed invention and prior ones are such that the claimed invention as a whole would have been obvious, then the claimed invention is rejected due to "obviousness."

181. If an examiner rejects a patent application, the USPTO will issue a Non-Final Rejection and the applicant is given the opportunity to make amendments or argue against the examiner's objections.

182. A Final Rejection is typically issued during second or subsequent examinations of the pending patent application and will also explain the reasons for the rejection.

183. The Final Rejection is intended to close prosecution of the pending patent application. An applicant whose patent application has been rejected may appeal the decision.

2. The USPTO Process For Communicating Agency Actions

184. The Patent Application Information Retrieval ("PAIR") is the USPTO's web-based means of electronically viewing the status of patent applications.

185. Public PAIR provides access to status and history information for issued patents and published applications. In a published application's PAIR page, the USPTO posts all actions taken, and related dates, with respect to the application.

186. Private PAIR provides access to non-public patent information, as well as all public information. Private PAIR allows those who register the ability to access real time status information, application documents and transaction history for their pending patent applications.

187. Entities and individuals with access to Private PAIR typically sign up for the e-Office Action Program which is designed to notify applicants, via email, that a USPTO communication is available for viewing and downloading in Private PAIR.

188. Typically, entities that have a patent application pending and have opted for Private PAIR and the e-Office Action Program will register their patent attorneys and Chief Technology Officers and/or those in charge of their intellectual property. Most entities with patent applications register for Private PAIR and the e-Office Action Program.

189. The method by which an applicant is notified of Non-Final and Final Rejections (via mail, email or both) depends on whether the applicant has registered for Private PAIR and the e-Office Action Program.

3. PolarityTE's Statements Regarding The SkinTE Patent Application Made Before The Class Period

190. On November 30, 2015, Defendant Lough filed a U.S. Patent Application, Application No. 14/954,335 referred to herein as the November 2015 SkinTE Patent Application. The November 2015 SkinTE Patent Application publication described the technology as "methods for development and use of minimally polarized function cell micro-aggregate units in tissue applications using LGR4, LGR5 and LGR6 expressing epithelial stem cells." The November 2015 SkinTE Patent Application is – up until the time of this filing – an application and ***not*** an issued patent, despite misleading and contradictory statements issued by PolarityTE.

191. Despite the fact that PolarityTE only had a patent application, in a December 7, 2016 Form 8-K, and in a December 8, 2016 press release announcing the Agreement, PolarityTE falsely stated that it was "***the owner of a novel regenerative medicine and tissue engineering platform developed and patented*** by Denver Lough, MD, PhD." (Emphasis supplied.)

192. In a January 10, 2017 press release announcing its name change from Majesco to PolarityTE, PolarityTE stated that it was "the owner of ***patent applications***." (Emphasis supplied.) In fact, PolarityTE was the owner of *only one* patent application.

193. In a January 30, 2017 SEC Form S-1, PolarityTE once again stated that it was "the owner of ***patent applications****."* (Emphasis supplied).

194. However, on February 9 and 16, 2017 press releases, PolarityTE once again falsely stated that, "***PolarityTE, Inc. is the owner of a novel regenerative medicine and tissue engineering platform developed and patented*** by Denver Lough MD, PhD." (Emphasis supplied).

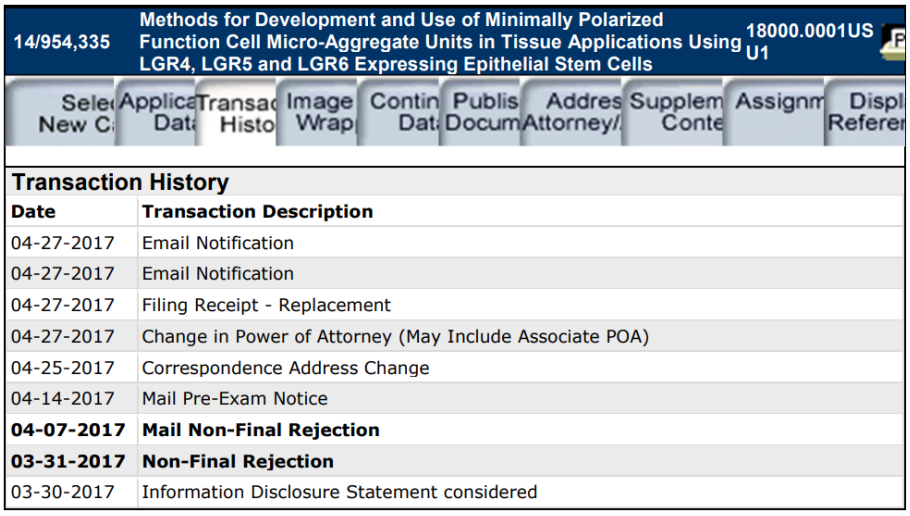
195. In a February 22, 2017 letter to the SEC regarding PolarityTE's Registration Statement on Form S-1, PolarityTE reverted to calling the November 2015 SkinTE Patent Application an application and not "patented." The letter stated, "Dr. Lough is the named inventor under a pending patent application…the Company is seeking to acquire the pending patent application."

196. However, in March 8, and 13, 2017 press releases, PolarityTE once again falsely stated that, "***PolarityTE, Inc. is the owner of a novel regenerative medicine and tissue engineering platform developed and patented*** by Denver Lough MD, PhD." (Emphasis supplied).

4. PolarityTE Receives A Non-Final Rejection Of The November 2015 SkinTEPatent Application

197. The November 2015 SkinTE Patent Application's Public PAIR page states that on March 31, 2017 the USPTO issued and posted its decision to render a Non-Final Rejection of the patent application.

198. The PAIR page also shows that on April 7, 2017, the same day that the Merger closed, the USPTO also mailed the Non-Final Rejection.



14/954,335 Methods for Development and Use of Minimally Polarized Function Cell Micro-Aggregate Units in Tissue Applications Using LGR4, LGR5 and LGR6 Expressing Epithelial Stem Cells 18000.0001US U1

Sele New C | Applica Data | Transac Histo | Image Wrap | Contin Data | Publis Docum | Addres Attorney/ | Supplem Conte | Assignm | Displ Referer

Transaction History

Date	Transaction Description
04-27-2017	Email Notification
04-27-2017	Email Notification
04-27-2017	Filing Receipt - Replacement
04-27-2017	Change in Power of Attorney (May Include Associate POA)
04-25-2017	Correspondence Address Change
04-14-2017	Mail Pre-Exam Notice
04-07-2017	**Mail Non-Final Rejection**
03-31-2017	**Non-Final Rejection**
03-30-2017	Information Disclosure Statement considered

199. As discussed on ¶¶ 185-188, most entities would have registered for Private PAIR and the e-Office Action program and would have received real time, same business day notification of the Non-Final Rejection of patent application.

200. A patent application is rejected if the examiner determines that the invention does not comply with 35 U.S.C. § 103; §111(a) (requirement for adequate description); or § 112(a) (considered "obvious").

201. The USPTO arrived at these determinations with respect to the November 2015 SkinTE Patent Application, finding that the specification provided did not adequately describe the subject matter and finding the alleged invention to be "obvious."

202. As previously mentioned, on April 7, 2017, PolarityTE filed a Form 8-K announcing the Merger. The Form 8-K also stated (emphasis supplied): "***Polarity[te] NV is the owner of a novel regenerative medicine and tissue engineering platform developed and patented by Dr. Lough.***"

203. On April 14, 2017, the SEC sent a letter to PolarityTE regarding the Company's preliminary proxy statement on Schedule 14A which was filed on February 6, 2017. The SEC informed the Company that it had completed its review of the filing and added (emphasis

supplied): *"We remind you that the company and its management are responsible for the accuracy and adequacy of their disclosures…"*

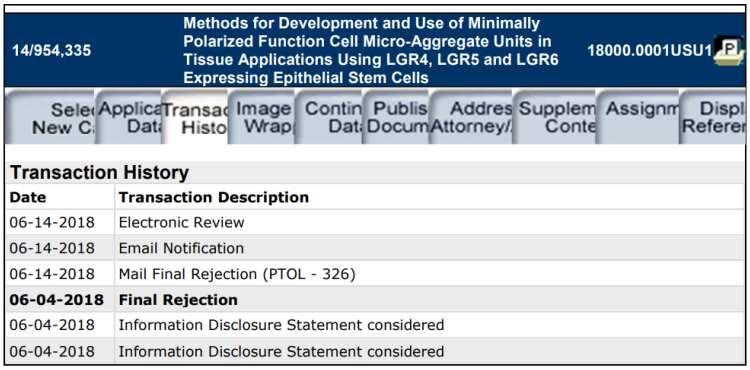
204. Subsequent to receiving the Non-Final Rejection, PolarityTE issued various statements respecting the November 2015 SkinTE Patent Application, patents generally, as well as statements discussing intellectual property risks in generic terms, while never disclosing the Non-Final Rejection for its leading product and its only asset at the time.

5. PolarityTE Receives A Final Rejection Of The November 2015 SkinTE Patent Application Before Raising Cash

205. On May 29, 2018, the Company filed an S-8 registration with the SEC, which allowed management and promoters to sell hundreds of millions of dollars of common stock.

206. On June 4, 2018, PolarityTE announced an offering of 2.1 million shares priced at $25.50 per share.

207. The November 2015 SkinTE Patent Application's Public PAIR page states that on June 4, 2018 the USPTO issued and posted its decision to render a Final Rejection of the patent application.



14/954,335	Methods for Development and Use of Minimally Polarized Function Cell Micro-Aggregate Units in Tissue Applications Using LGR4, LGR5 and LGR6 Expressing Epithelial Stem Cells	18000.0001USU1

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Transaction History

Date	Transaction Description
06-14-2018	Electronic Review
06-14-2018	Email Notification
06-14-2018	Mail Final Rejection (PTOL - 326)
06-04-2018	**Final Rejection**
06-04-2018	Information Disclosure Statement considered
06-04-2018	Information Disclosure Statement considered

208. The November 2015 SkinTE Patent Application was rejected under 35 U.S.C. § 103. The USPTO issued the Final Rejection after concluding, that even after PolarityTE's amendments, the claimed invention "as a whole would have been obvious before the effective filing date." The Final Rejection letter concluded (emphasis in original): "No claim is allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**."

209. A rejection is intended by the USPTO to close prosecution of the pending patent application. According to a Yale study, less than 10% of patent applications that receive a Final Rejection subsequently get issued. Additionally, Evercore ISI, which recently initiated coverage on PolarityTE also noted that roughly 10% of applications with Final Rejections ultimately get approval.

210. On June 5, 2018, PolarityTE issued a press release announcing the pricing of the underwritten public follow-on offering of approximately $55 million of shares of its common stock. While the press release touted PolarityTE's "platform technology" no mention was made of the fact that the USPTO had issued a Final Rejection of the November 2015 SkinTE Patent Application – the Company's signature technology which is purported to form the basis for their "platform technology" and PolarityTE's commercial success.

211. Subsequent to receiving the Final Rejection, PolarityTE issued various statements discussing intellectual property risks in generic terms, while never disclosing the Final Rejection for its leading product.

C. Defendants Knew About But Failed To Disclose Receipt Of An FDA Form 483

1. The FDA Inspection Process And The Purpose Of FDA Form 483

212. If an establishment manufactures human cells, tissues, and cellular and tissue-based products (HCT/Ps) (as discussed below, SkinTE is an HCT/P) the establishment must permit the FDA to inspect any manufacturing location to determine compliance with the provisions of Part 1271.

213. Investigators note facts that, in their judgment, ***constitute violations of FDA standards***. A Form 483 is intended for use in notifying the inspected establishment's ***top***

management in writing of ***significant objectionable conditions***, relating to products and/or processes, or other violations of the FD&C Act and related Acts which were observed during the inspection.

214. The FDA instructs its investigators that all observations recorded in a Form 483 ***should be significant and correlate to regulated products or processes being inspected.***

215. At the end of the inspection process, FDA investigators must present a hard copy of the Form 483 to the highest-ranking "owner, operator or agent in charge."

2. Section 361 HCT/Ps Must Comply With Current Good Tissue Practices ("cGTPs")

216. Subpart D of Part 1271 sets forth cGTP requirements which govern the methods used in, and the facilities and controls used for, the manufacture of HCT/Ps.

217. ***Establishment and Maintenance of a Quality Program.*** **Part 1271.60.** An organization's quality program must ensure that the establishment complies with the requirements for procedures relating to core cGTP requirements, must ensure appropriate corrective actions, proper documentation and appropriate monitoring systems as necessary.

218. ***Procedures.*** **Part 1271.80.** The HCT/Ps manufacturing facility must establish and maintain procedures appropriate to meet core cGTP requirements for all steps that are performed in the manufacture of HCT/Ps.

219. ***Facilities.*** **Part 1271.190.** Any facility used in the manufacture of HCT/Ps must be of suitable size, construction, and location to prevent contamination of HCT/Ps.

220. ***Environmental Controls and Monitoring.*** **Part 1271.195.** Where environmental conditions could reasonably be expected to cause contamination or cross-contamination of HCT/Ps or equipment, there must be adequate control of environmental conditions and proper conditions for operations.

3. PolarityTE's Failure To Comply With FDA Regulations

a) SkinTE Was Required To Comply With Current Good Tissue Practices (cGTPs) And Was Subject To FDA Inspections

221. Because, as discussed *infra* ¶¶ 244-245, PolarityTE registered SkinTE as an HCT/P under Section 361, SkinTE and PolarityTE's facilities used in the manufacture of SkinTE, were required to comply with Subpart D of Part 1271.

222. PolarityTE's 2017 10-K demonstrates that the Company understood that it needed to comply with cGTP requirements (emphasis supplied): "***Products that qualify as 361 HCT/Ps**…**are subject to postmarket regulatory requirements such as compliance with current good tissue practices (cGTP)**…*and post-market inspections by the FDA."

223. PolarityTE also understood that it was subject to inspections by the FDA. As stated in the Company's 2017 10-K (emphasis supplied): ***"FDA inspection and enforcement with respect to establishments described in 21 C.F.R. § 1271 includes inspections conducted**…*"

224. Furthermore, PolarityTE also understood that if it failed to comply with FDA regulations, which encompassed compliance with cGTPs, it would be subject to enforcement action (emphasis supplied): "***If we fail to comply with the FDA regulations and laws applicable to our operation or tissue products***, the ***FDA could take enforcement action**…*"

b) The FDA Form 483 Issued To PolarityTE Demonstrates That The Company Failed To Comply With cGTPs And FDA Regulations

225. In July 2018, FDA inspectors conducted an examination of PolarityTE's Salt Lake establishment where the SkinTE product was manufactured. The inspection took place between July 9 and July 13, 2018.

226. On July 13, 2018, at the conclusion of the inspection, an FDA Form 483 was issued to PolarityTE's Director of Quality, Andrew D. West, and the observations therein were discussed with him.

227. PolarityTE's complete lack of controls in the manufacturing of the SkinTE product resulted in eight separate observed violations of FCA regulations respecting compliance with cGTPs.

228. Specifically, Observation 1 found (emphasis supplied):

> There are ***no written procedures for production and process controls…***
>
> Your firm ***has not performed and documented quantitative data that validates your process for SkinTE*** product…
>
> Your Director of Quality has stated ***the process "is more of an art than a science".***

229. The violations denoted in Observation 1 are violations of Part 1271.80, which requires establishments to maintain procedures appropriate to meet core cGTP requirements for all steps performed in the manufacture of the HCT/Ps.

230. Specifically, Observation 2 found (emphasis supplied):

> Buildings used in the manufacture, processing, packing, or holding of a drug product ***do not have the suitable construction to facilitate cleaning, maintenance, and proper operations***.
>
> Specifically, ***clean room is not adequately designed and built***…
>
> I observed processing of SkinTE product…***the processing room was in use without positive pressure…***
>
> ***The air handlers controlling air temperature and humidity in the plenum are designed only for recirculation without fresh air intake***…

231. The violations denoted in Observation 2 are violations of Part 1271.190, which requires that any facility used in the manufacture of HCT/Ps be of suitable of size, construction and location to prevent contamination. Additionally, the violations denoted in Observation 2 are

violations of Part 1271.195(a)(1) and (a)(2), which require adequate environmental controls respecting temperature and humidity and ventilation and air filtration.

232. Specifically, Observation 3 found (emphasis supplied):

> ***Aseptic processing areas are deficient regarding the system for monitoring environmental conditions.***
>
> Specifically, your firm ***does not adequately monitor the ISO 7 environment used as a processing room that houses hoods for handling SkinTE product***.
>
> Also, your firm is ***not collecting air and surface samples within the ISO 7 processing room on a routine basis*** and there is ***no written procedure for routine monitoring of the processing*** room…

233. The violations denoted in Observation 3 are violations of Part 1271.195, which requires adequate environmental controls. Additionally, the violations denoted in Observation 3 are violations of Part 1271.80, which requires the establishment to establish and maintain procedures appropriate to meet the core cGTP requirements.

234. Specifically, Observation 4 found (emphasis supplied):

> There is ***no written testing program designed to assess the stability characteristics of drug products***.
>
> Specifically, ***the expiry of assigned to SkinTE products is not supported by adequately documented data***.
>
> Additionally, data…related to the viability of cells in ***SkinTE does not include the following documentation to establish as pertinent to commercial product***…

235. The violations denoted in Observation 4 are violations of Part 1271.180, which requires establishments to maintain procedures appropriate to meet core cGTP requirements for all steps performed in the manufacture of the HCT/Ps.

236. Specifically, Observation 5 found (emphasis supplied):

> The ***quality control unit lacks authority to fully investigate errors*** that have occurred.

> Specifically, your firm ***does not have a written procedure to define or document an acceptable quantity, identity, or trend of bioburden within the SkinTE product***, above/outside of which a deviation or investigation would be initiated.

237. The violations denoted in Observation 5 are violations of Part 1271.180, which requires establishment and maintenance of a quality program designed to prevent, detect, and correct deficiencies and ensure that the establishment complies with the requirements for procedures relating to core cGTP requirements.

238. Specifically, Observation 6 found (emphasis supplied):

> ***Established laboratory control mechanisms are not followed and documented*** at the time of performance.
>
> Specifically, ***continuous or consistent temperature monitoring of microbial incubation samples for SkinTE product samples is not performed or documented***…
>
> Additionally, your Director of Manufacturing Operations stated that ***differential pressures for the processing room where SkinTE product is handled inside, is not documented and there is no written procedure*** for such record….

239. The violations denoted in Observation 6 are violations of Part 1271.180, which requires establishment and maintenance of a quality program designed to prevent, detect, and correct deficiencies and ensure that the establishment complies with the requirements for procedures relating to core cGTP requirements. Additionally, the violations denoted in Observation 6 are also violations of Part 1271.180, which requires establishments to maintain procedures appropriate to meet core cGTP requirements for all steps performed in the manufacture of the HCT/Ps.

240. Specifically, Observation 7 found (emphasis supplied):

> ***Aseptic processing areas are deficient regarding the system for cleaning and disinfecting the room*** to produce aseptic conditions.
>
> Specifically, cleaning is not performed for processing SkinTE inside the ISO 7 room.

241. The violations denoted in Observation 7 are violations of Part 1271.195(a)(3), which requires environmental controls and monitoring respecting cleaning and disinfecting of rooms to ensure aseptic processing operations.

242. Specifically, Observation 8 found (emphasis supplied):

> ***Separate or defined areas to prevent contamination or mix-ups are deficient regarding the manufacturing and processing operations***.

243. The violations denoted in Observation 8 are violations of Part 1271.195, which, requires any facility used in the manufacture of HCT/Ps to be of suitable size, construction, and location to prevent contamination and ensure orderly handling of without mix-ups.

D. Defendants Knew SkinTE Registration Under Section 361 Was Improper

244. On October 3, 2017, Defendants first announced that SkinTE had been registered under Section 361, and then repeatedly stated that as fact throughout the rest of the Class Period.

245. At all relevant times, SkinTE did not meet the criteria for regulation solely under Section 361. Defendants could not reasonably have concluded otherwise.

1. The FDA Regulatory Scheme For Regulating Human Cellular And Tissue-Based Products

246. Sections 351 and 361 of the PHS Act provide the FDA with the authority to establish regulatory requirements for marketing traditional biologics and HCT/Ps. These two "regulatory pathways" differ in terms of time, effort and expense required to bring these products to market.

247. Section 351 of the PHS Act is intended to regulate traditional biologics. Section 361 of the PSH Act does not identify a class of products, but rather authorizes the FDA to issue regulations to prevent the introduction, transmission, or spread of communicable disease.

248. Subpart A of Part 1271 sets forth general provisions, including the definition of a 361 HCT/P eligible for regulation solely under Part 1271. Part 1271.3(d) defines HCT/Ps as,

"articles containing or consisting of human cells or tissues that are intended for implantation, transplantation, infusion, or transfer into a human recipient.

249. After determination that a product meets the HCT/P definition in Part 1271.3(d), in order to determine if the **HCT/P is regulated solely under Section 361, it must meet all of the criteria set out in Part 1271.10(a):**

> **(a)** An HCT/P is regulated solely under section 361 of the PHS Act and the regulations in this part if it meets all of the following criteria:
>
> **(1)** The HCT/P is minimally manipulated;
>
> **(2)** The HCT/P is intended for homologous use only, as reflected by the labeling, advertising, or other indications of the manufacturer's objective intent;
>
> **(3)** The manufacture of the HCT/P does not involve the combination of the cells or tissues with another article, except for water, crystalloids, or a sterilizing, preserving, or storage agent, provided that the addition of water, crystalloids, or the sterilizing, preserving, or storage agent does not raise new clinical safety concerns with respect to the HCT/P; and
>
> **(4)** Either:
>
> **(i)** The HCT/P does not have a systemic effect and is not dependent upon the metabolic activity of living cells for its primary function; or
>
> **(ii)** The HCT/P has a systemic effect or is dependent upon the metabolic activity of living cells for its primary function, and:
>
> ***(a)*** Is for autologous use;
>
> ***(b)*** Is for allogeneic use in a first-degree or second-degree blood relative; or
>
> ***(c)*** Is for reproductive use.

2. Regulation Of HCT/Ps Under Section 351 Is More Burdensome, Expensive And Time Consuming Than Regulation Under Section 361

250. Biologics that are regulated by the FDA under Section 351 require FDA approval of a Biologics License Application ("BLA") and are required to obtain premarket approvals and clearance from the FDA. The BLA application requirements are extensive and include requests for clinical data.

251. Additionally, the biologics regulated under Section 351 may require an Investigational New Drug Application ("IND") which is a request for authorization from the FDA to administer an investigational drug or biological product to humans. The IND application requirements are also extensive.

252. In addition to the extensive BLA application process, regulation under Section 351 is both time consuming and costly. For example, the time to market from first development is typically over 10 years and development costs can run well into the billions.

253. On the other hand, HCT/Ps that are marketed solely under Section 361 are not required to obtain premarket approval/clearance from the FDA and do not require the extensive registration, manufacturing, and reporting steps required under Section 351 since the marketers of HCT/Ps are permitted to self-designate. The time to market for a Section 361 HCT/P is typically one to two years and the development costs run around $1 million.

3. The FDA Provides Resources To Assist With The Determination Of What Is The Appropriate Classification Of An HCT/P

254. The Tissue Reference Group ("TRG") was created by the FDA for the purpose of providing a single reference point for product specific questions concerning jurisdiction and applicable regulation of HCT/Ps. Furthermore, a Request for Designation ("RFD") may be submitted to the Office of Combination Products ("OCP") to obtain a formal FDA decision regarding the regulatory identity or classification of an HCT/P.

255. Additionally, the FDA has issued three guidance documents, dated December 2014, October 2015 and November 2017 (corrected December 2017) in order to provide the industry with guidance on the FDA's "current thinking" respecting how to interpret Part 1271: December 2014 Guidance; October 2015 Guidance; 2017 Guidance.

256. The 2017 Guidance states that, "[t]he interpretation of the minimal manipulation and homologous use criteria and definitions of related key terms have been of considerable interest to industry stakeholders since the criteria and definitions were first proposed" and purports to provide specific guidance on the FDA's "current thinking" regarding Part 1271.10(a)(1) criterion of minimal manipulation and the Part 1271.10(a)(2) criterion of homologous use. The Guidance was intended to "facilitate stakeholders' understanding" of how these regulatory criteria apply to their HCT/Ps.

4. Defendants Provided A Description Of SkinTE And The Technology Behind It Which Demonstrated That SkinTE Could Not Qualify For Regulation Solely Under Section 361

257. On October 3, 2017, PolarityTE issued a press release announcing that it had registered SkinTE with the FDA pursuant to Section 361. Through the Class Period, PolarityTE represented that SkinTE was subject to regulation by the FDA *solely* under 361. These statements were materially false and misleading because the SkinTE product, as described by Defendants, does not meet the criteria for regulations solely under Section 361.

258. In December 2014, Defendant Lough filed a provisional patent application (62/086,526) ("Provisional Application"). Defendant Lough filed the November 2015 SkinTE Patent Application on November 30, 2015. The November 2015 SkinTE Patent Application notes that it is related to the Provisional Application and both appear to address the technology and purported invention underlying the SkinTE product.

259. The SkinTE technology invention appears to focus on a special population of LGR4, LGR5 and LGR6 expressing cells potentially supported by a matrix, scaffolding and supplemental growth factors.

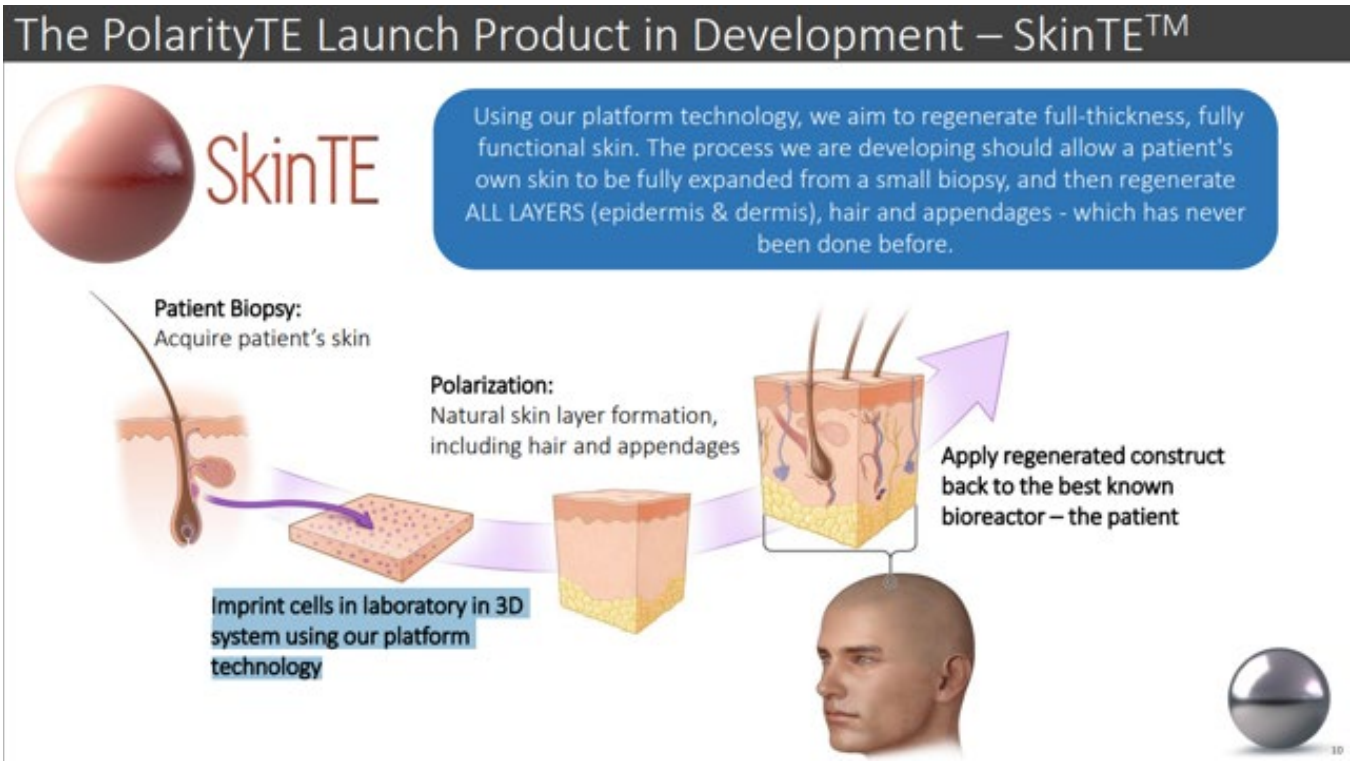
260. PolarityTE filed two subsequent patent applications on July 14, 2017. These patent applications (15/650,656 and 15/650,659) are noted as related to the November 2015

SkinTE Patent Application and address the same technology and purported invention underlying the SkinTE product.

261. The data behind the SkinTE technology, as reflected in the November 2015 SkinTE Patent Application, appears to be contained in two papers authored by Defendant Lough in 2013 and 2016. Additionally, earlier versions of the papers formed part of the submitted specification associated with the Provisional Application.

262. The Lough 2016 paper describes a procedure calls for the isolation of a population of LGR6 expressing epithelia cells which is then cultured in a growth hormone containing medium, is then allowed to adhere to a matrix, and is thereafter placed in a murine wound model. The procedure is therefore presented as a "new method of providing skin to those wound beds that are intrinsically incapable of healing themselves."

263. A June 29, 2017 Business Presentation, titled "NASDAQ: COOL PolarityTE where self regenerates self," contains a slide describing the SkinTE process. The description of the process, as well as the graphics in the slide, represent a procedure that appears to mirror tissue engineering which involves the use of a tissue scaffold for the formation of new viable tissue.



264. PolarityTE's Form 2017 10-K Report, provides more relevant descriptions of the SkinTE product and the underlying technology, stating (emphasis supplied):

- SkinTE is ***created from a small piece of the patient's own tissue***…to expand and ***regenerate full-thickness, fully functional skin***
- We use proprietary techniques ***to create a paste-like product*** from the small piece of healthy patient tissue.

265. PolarityTE's Form 2017 10-K Report also describes the procedure and strategy behind how the SkinTE product would function, stating that (emphasis supplied): "With SkinTE, often ***within 24-48 hours of the initial skin harvest, our product is applied to the patient***.."

266. Finally, a February 17, 2018 Salt Lake Tribute article titled "This Salt Lake City startup says its stem cell treatment will regenerate skin…" purports to contain information provided by PolarityTE, and mentions the use of "growth factors" in the process (emphasis supplied): "***The cells are placed into a paste that includes growth*** **factors Ñ substances**."

5. SkinTE Had No Basis To Seek Regulation Solely Under Section 361

267. An HCT/P of the kind underlying the SkinTE product is eligible for regulation ***solely*** under Section 361 ***only*** if it meets the criteria set out in Part 1271.10 (a).

268. A review of the November 2015 SkinTE Patent Application and related patent applications, the Lough Papers (which describe the processes underlying the SkinTE product) and PolarityTE's description of the SkinTE product in its SEC filing and business presentation demonstrates that SkinTE does not qualify for regulation under Section 361.

a) SkinTE Does Not Meet The "Minimally Manipulated" Prong Under Part 1271(a)(1)

269. Under Part 1271(a)(1), an HCT/P can be regulated *solely* under Section 361 if it has been *only* "minimally manipulated."

270. Part 1271.3(f) defines what entails "minimally manipulated" depending on whether the HCT/P is considered "structural tissue" or "cells or nonstructural tissue."

271. The 2017 Guidance considers skin a "structural tissue." The 2017 Guidance also explains that skin is a structural tissue which "physically support[s] or serve[s] as a barrier or conduit, cover, or cushion in the donor." (pg. 7).

272. Thus, under Part 1271.3(f)(1), "for structural tissue", "minimally manipulated" means "processing that does not alter the original relevant characteristics of the tissue relating to the tissue's utility for reconstruction, repair or replacement."

273. PolarityTE's 2017 10-K and the June 2017 Business Presentation, describe the SkinTE product as entailing the excision of full-thickness skin, which is then processed –using PolarityTE's "platform technology" – to yield a paste which is applied back to the patient.

274. On its face, the creation of a "paste" from skin, exceeds minimal manipulation because it "alter[s] the original relevant characteristics of the" skin which is to "physically support[s] or serve[s] as a barrier or conduit, cover, or cushion in the donor."

275. The 2017 Guidance provides an analogous method used as an example of the type of processing which is considered more than "minimally manipulated" (emphasis supplied): "A manufacturer ***processes skin by removing the epidermis*** and then ***grinding the dermis into particles***…is considered ***more than minimally manipulated*** because the processing ***alters the original relevant characteristics of skin*** related to its utility as a protective covering."

276. It would follow that if the removal of dermis and its subsequent grinding into particles is considered more than "minimally manipulated" processing, so would be the removal and grinding of skin into a paste.

b) SkinTE Does Not Meet The "Homologous Use" Prong Under Part 1271(1)(2)

277. Under Part 1271(a)(2), an HCT/P can be regulated *solely* under Section 361 if the HCT/P is intended for homologous use only.

278. Part 1271.3(c) defines "homologous use" as "the repair, reconstruction, replacement, or supplementation of a recipient's cells or tissues with an HCT/P that ***performs the same basic function or functions*** in the recipient as in the donor." (Emphasis supplied.)

279. Under the 2017 Guidance (emphasis supplied): "The ***basic function of an HCT/P is what it does from a biological/physiological point of view, or is capable of doing when in its native state…Basic functions are well understood***; it ***should not be necessary to perform laboratory, preclinical, or clinical studies to demonstrate***…"

280. Thus, under the 2017 Guidance construction of what is a "basic function" – for purposes of determining "homologous use" – the SkinTE product's "basic" function of

"regenerating full-thickness skin" would have to be so easily understood that no laboratory, preclinical or clinical studies would be required.

281. The Lough 2016 Paper readily admits that it "seek[s] to determine" whether the LGR6 cell population is effective for translational use. If the function of SkinTE were indeed as "basic" as contemplated by the FDA, there would be no need for PolarityTE to conduct preclinical trials or trials of any sort to explain the function of the product; and, the experiments described in the Lough Papers intended to clarify the cell population at issue would not be necessary.

282. In sum, the description of the SkinTE product as one that "regenerates full-thickness hair bearing skin" is a claim beyond a "basic function" under homologous use.

c) SkinTE Does Not Meet The No "Combination" With "Another Article" Prong Under Part 1271(3)

283. Under Part 1271(a)(3), an HCT/P can be regulated *solely* under Section 361 if "the ***manufacture of the HCT/P does not involve the combination of the cells or tissues with another article***, except for water, crystalloids… (emphasis supplied).

284. By definition, under Part 1271(a)(3), an HCT/P would not be subject to regulation *solely* pursuant to Section 361 if it is mixed with a carrier or if it is treated with supplements, such as growth hormone/factors or enzymes, during manufacture.

i. SkinTE Entails The Use Of Growth Factors

285. Defendant Lough's Papers explicitly note that the process involves culturing with various growth factors – fetal bovine serum, endothelial growth factor and basic fibroblast growth factor. The process also entails the addition of insulin and hydrocortisone:

286. Also, as noted, *supra* ¶ 266, PolarityTE has described one of the steps in the formulation of SkinTE as entailing the combination of growth factors.

287. Additionally, the application 15/650,659 also mentions the use of growth factors in the process (emphasis supplied): "The method…consisting of ***growth factors***..."

ii. SkinTE Entails The Use Of Digestive Enzymes

288. Patent application 15/650,659 mentions the use of digestive enzymes in the SkinTE process. The application explains how the received samples are processed and turned into the necessitated paste with the use of enzymes (emphasis supplied): " by ***placing the specimen into 50 ml conical tube containing MSC Enzymatic Digestive Media, a pre-mixed digestive enzyme solution (collagenase and dispase-based)…***

iii. SkinTE Entails The Use Of Scaffolding

289. The Lough 2016 paper specifically references the use of scaffolding: "the LGR6 epithelial stem… ***seeded onto a spectrum of acellular scaffolds***…Lough 2016 (emphasis supplied).

290. The November 2015 SkinTE Patent Application also mentions the use of scaffolding (emphasis supplied): "including isolated living LGR expressing cells and a ***multi-dimensional support selected from the group consisting of scaffolding***, collagen, matrix, particle…"

291. The patent application 15/650,659 also mentions the use of scaffolding (emphasis supplied): "LGR expressing cells to a multidimensional support selected from the group ***consisting of scaffolding, collagen, matrix, particle, and fiber***.

292. Also, as described in the slide, *supra* ¶ 263, a June 2017 PolarityTE presentation, provides a graphic, which shows the process being akin to tissue engineering scaffolding.

293. In conclusion, a review of Defendants' various materials: the Lough Papers, the November 2015 SkinTE Patent Application, the July 2017 patent applications, and descriptions of the SkinTE process provided by PolarityTE in articles and business presentations, coupled

with an analysis of the requirements for Section 361 regulation and the 2017 Guidance, undoubtedly demonstrates that SkinTE is afoul of ***all three*** pertinent Section 361 requirements and is not an HCT/P that qualifies for regulation under the Section.

294. Eventually, PolarityTE removed both the scaffold and growth factors from the marketed version of SkinTE, as reflected in an investor presentation at Jeffries 2018 Global Healthcare Conference. Notwithstanding, SkinTE still does not satisfy the Section 361 requirements.

6. PolarityTE Knew That SkinTE Should Have Been Registered For Regulation As A Section 351 Product But Chose To Register SkinTE As A Section 361 HCT/P In Order To A Avoid The Burdensome Requirements Under Section 351

295. Because SkinTE did not quality for regulation under Section 361, it was subject to regulation under the FDCA and/or Section 351. As explained, *supra* ¶¶ 250-253, regulation under Section 351 is extraordinarily more burdensome than regulation under Section 361 because it entails premarket approvals and clearance from the FDA, as well as related costs. Additionally, a product brought to market under Section 351 can expect a time to market of 10 years after first development. In contrast, PolarityTE's various SEC filings contemplated bringing to market the various "TE" "platform" products within two years of development.

296. On October 25, 2017, *Seeking Alpha* published an article by White Diamond Research titled, "PolarityTE: A Comprehensive Look At The Bull Vs. Bear Cases. In that article, the author references a discussion with Defendant Stetson where Stetson noted the smaller market for Epicel and Vericel as a result of their FDA approval. He praised PolarityTE's ability to address any market because it was not restricted to only the market for which it had FDA approval, since it never actually sought or received FDA approval. This tends to indicate that business strategy was the primary reason PolarityTE chose to register under Section 361, instead of the belief that SkinTE properly fell under the Section 361 provisions.

297. PolarityTE's SEC filings demonstrate that the Company was intimately aware of the process behind designation of an HCT/P as regulated under Section 361. The Company's SEC Form 10-K for the fiscal year ended October 31, 2017 ("2017 10-K) stated (emphasis added): "In the United States, ***HCT/Ps are subject to varying degrees of regulation by the FDA, depending on if they fall solely within the scope of Section 361***…If an HCT/P meets the criteria for regulation solely under Section 361…no premarket FDA review for safety and effectiveness under a drug, device, or biological product marketing application is required."

298. PolarityTE's 2017 10-K also demonstrates that the Company understood how burdensome it would be to bring SkinTE, and the technology behind it, to market under Section 351 (emphasis supplied): "***Manufacturers of new drugs, biologics and some medical devices must complete extensive clinical trials, which must be conducted pursuant to an effective IND or IDE. In addition, the FDA must review and approve a BLA or NDA before a new drug or biologic may be marketed. For most medical devices, including novel or high-risk medical devices, FDA must approve a premarket approval application ("PMA") or grant clearance to a premarket notification ("510(k)") application prior to marketing of the device***…"

299. Additionally, PolarityTE's 2017 10-K notes the importance of the "minimally manipulated" and "homologous use" criteria in the context of Section 361 (emphasis supplied): "The FDA's criteria for regulation as a 361 HCT/P are complex, and ***the FDA has not provided comprehensive guidance on the meaning of certain terms used in the criteria, such as "minimal manipulation," "homologous,"*** or "combination of the cells and tissues with another article.""

300. However, the December 2014 Guidance and October 2015 Guidance, which were released years prior to the SkinTE's designation as a Section 361 product, provide meaningful guidance on key terms and interpretations which would have assisted PolarityTE in correctly

determining if SkinTE qualified for regulation under Section 361. For example, the Guidance stated (emphasis supplied): "***tissues that physically support or serve as a barrier or conduit, or connect, cover, or cushion are generally considered structural tissues*** for the purpose of applying the regulatory framework and you should ***consider whether the processing alters an original relevant characteristic of the tissue, relating to the tissue's utility for reconstruction, repair, or replacement as structural tissue***…A ***homologous use for a structural tissue*** would generally be to perform a structural function in the recipient, for example, ***to physically support or serve as a barrier or conduit, or connect, cover, or cushion***."

301. More relevant, by the time PolarityTE filed its 2017 10-K, on January 30, 2018, the 2017 Guidance had been released (November 2017, corrected December 2017), which, as discussed, *supra* ¶ 256, was released ***precisely*** because the interpretation of those two criteria had received considerable interest by industry stakeholders, the FDA wanted to provide guidance on its "current thinking" and it provided exacting examples that directly apply to the SkinTE process.

302. As stated in the Company's 2017 10-K, PolarityTE was aware that it had a duty to revise this designation if it arrived at a determination that its product did not meet the requirements under Section 361 (emphasis supplied): "All establishments that manufacture 361 HCT/Ps…are ***required to update*** their registration annually in December ***or within 30 days of certain changes, and submit changes in HCT/P listing***…"

303. Nevertheless, SkinTE continued to be registered as a Section 361 product throughout the Class Period and up to the present.

304. In addition to FDA guidance, as discussed, *supra* ¶ 254, the FDA has bodies dedicated to helping manufacturers determine classification of their products. According to PolarityTE's SEC filings, it chose not to approach the FDA for guidance despite the fact that by

its own admission SkinTE and the "platform technology" are a "novel approach", which, would have benefitted from FDA guidance early on.

305. Because PolarityTE knew of the requirements for regulation under Section 361, had access to FDA guidance, and knew the formulation behind the SkinTE process, it is clear that the Company had no reasonable basis for concluding that its Skin TE product met the requirements for regulation under Section 361 and its representations that SkinTE was regulated under Section 361 were materially false and misleading.

VII. PLAINTIFF'S CLASS ACTION ALLEGATIONS

306. Plaintiff brings this action as a class action pursuant to Federal Rule of Civil Procedure 23(a) and (b)(3) on behalf of a Class, consisting of all those who purchased or otherwise acquired the publicly traded securities of PolarityTE during the Class Period (the "Class"); and were damaged upon the revelation of the alleged corrective disclosures. Excluded from the Class are Defendants herein, the officers and directors of the Company, at all relevant times, members of their immediate families and their legal representatives, heirs, successors or assigns and any entity in which Defendants have or had a controlling interest.

307. The members of the Class are so numerous that joinder of all members is impracticable. Throughout the Class Period, PolarityTE securities were actively traded on the NASDAQ. While the exact number of Class members is unknown to Plaintiff at this time and can be ascertained only through appropriate discovery, Plaintiff believes that there are hundreds or thousands of members in the proposed Class. Record owners and other members of the Class may be identified from records maintained by PolarityTE or its transfer agent and may be notified of the pendency of this action by mail, using the form of notice similar to that customarily used in securities class actions.

308. Plaintiff's claims are typical of the claims of the members of the Class as all members of the Class are similarly affected by Defendants' wrongful conduct in violation of federal law that is complained of herein.

309. Plaintiff will fairly and adequately protect the interests of the members of the Class and has retained counsel competent and experienced in class and securities litigation. Plaintiff has no interests antagonistic to or in conflict with those of the Class.

310. Common questions of law and fact exist as to all members of the Class and predominate over any questions solely affecting individual members of the Class. Among the questions of law and fact common to the Class are:

- whether the federal securities laws were violated by Defendants' acts as alleged herein;
- whether statements made by Defendants to the investing public during the Class Period misrepresented material facts about the financial condition, business, operations, and management of PolarityTE;
- whether Defendants caused PolarityTE to issue false and misleading financial statements during the Class Period;
- whether Defendants acted knowingly or recklessly in issuing false and misleading financial statements;
- whether the prices of PolarityTE securities during the Class Period were artificially inflated because of Defendants' conduct complained of herein; and
- whether the members of the Class have sustained damages and, if so, what is the proper measure of damages.

311. A class action is superior to all other available methods for the fair and efficient adjudication of this controversy since joinder of all members is impracticable. Furthermore, as the damages suffered by individual Class members may be relatively small, the expense and burden of individual litigation make it impossible for members of the Class to individually

redress the wrongs done to them. There will be no difficulty in the management of this action as a class action.

312. Plaintiff will rely, in part, upon the presumption of reliance established by the fraud-on-the-market doctrine in that:

- Defendants made public misrepresentations or failed to disclose material facts during the Class Period;
- the omissions and misrepresentations were material;
- PolarityTE common shares are traded in efficient markets;
- the Company's shares were liquid and traded with moderate to heavy volume during the Class Period;
- the Company traded on the NASDAQ, and was covered by multiple analysts;
- the misrepresentations and omissions alleged would tend to induce a reasonable investor to misjudge the value of the Company's common shares; and
- Plaintiff and members of the Class purchased and/or sold PolarityTE common shares between the time the Defendants failed to disclose or misrepresented material facts and the time the true facts were disclosed, without knowledge of the omitted or misrepresented facts.

313. Based upon the foregoing, Plaintiff and the members of the Class are entitled to a presumption of reliance upon the integrity of the market.

314. Alternatively, Plaintiff and the members of the Class are entitled to the presumption of reliance established by the Supreme Court in *Affiliated Ute Citizens of the State of Utah v. United States*, 406 U.S. 128, 92 S. Ct. 2430 (1972), as Defendants omitted material information in their Class Period statements in violation of a duty to disclose such information, as detailed above.

COUNT I

Violation Of Section 10(b) Of The Exchange Act And Rule 10b-5
Against All Defendants

315. Plaintiff repeats and realleges each and every allegation contained above as if fully set forth herein.

316. This Count is asserted against PolarityTE and the Individual Defendants and is based upon Section 10(b) of the Exchange Act, 15 U.S.C. § 78j(b), and Rule 10b-5 promulgated thereunder by the SEC.

317. During the Class Period, PolarityTE and the Individual Defendants, individually and in concert, directly or indirectly, disseminated or approved the false statements specified above, which they knew or deliberately disregarded were misleading in that they contained misrepresentations and failed to disclose material facts necessary in order to make the statements made, in light of the circumstances under which they were made, not misleading.

318. PolarityTE and the Individual Defendants violated §10(b) of the 1934 Act and Rule 10b-5 in that they:

- employed devices, schemes and artifices to defraud;
- made untrue statements of material facts or omitted to state material facts necessary in order to make the statements made, in light of the circumstances under which they were made, not misleading; or
- engaged in acts, practices and a course of business that operated as a fraud or deceit upon plaintiff and others similarly situated in connection with their purchases of PolarityTE common shares during the Class Period.

319. PolarityTE and the Individual Defendants acted with scienter in that they knew that the public documents and statements issued or disseminated in the name of PolarityTE were materially false and misleading; knew that such statements or documents would be issued or disseminated to the investing public; and knowingly and substantially participated, or acquiesced in the issuance or dissemination of such statements or documents as primary violations of the securities laws. These Defendants by virtue of their receipt of information reflecting the true

facts of PolarityTE, their control over, and/or receipt and/or modification of PolarityTE allegedly materially misleading statements, and/or their associations with the Company which made them privy to confidential proprietary information concerning PolarityTE, participated in the fraudulent scheme alleged herein.

320. Individual Defendants, who are the senior officers and/or directors of the Company, had actual knowledge of the material omissions and/or the falsity of the material statements set forth above, and intended to deceive Plaintiff and the other members of the Class, or, in the alternative, acted with reckless disregard for the truth when they failed to ascertain and disclose the true facts in the statements made by them or other PolarityTE personnel to members of the investing public, including Plaintiff and the Class.

321. As a result of the foregoing, the market price of PolarityTE common shares was artificially inflated during the Class Period. In ignorance of the falsity of PolarityTE's and the Individual Defendants' statements, Plaintiff and the other members of the Class relied on the statements described above and/or the integrity of the market price of PolarityTE common shares during the Class Period in purchasing PolarityTE common shares at prices that were artificially inflated as a result of PolarityTE's and the Individual Defendants' false and misleading statements.

322. Had Plaintiff and the other members of the Class been aware that the market price of PolarityTE common shares had been artificially and falsely inflated by PolarityTE's and the Individual Defendants' misleading statements and by the material adverse information which PolarityTE's and the Individual Defendants did not disclose, they would not have purchased PolarityTE's common shares at the artificially inflated prices that they did, or at all.

323. As a result of the wrongful conduct alleged herein, Plaintiff and other members of the Class have suffered damages in an amount to be established at trial.

324. By reason of the foregoing, PolarityTE and the Individual Defendants have violated Section 10(b) of the 1934 Act and Rule 10b-5 promulgated thereunder and are liable to the Plaintiff and the other members of the Class for substantial damages which they suffered in connection with their purchase of PolarityTE common shares during the Class Period.

COUNT II

Violation Of Section 20(a) Of The Exchange Act Against The Individual Defendants

325. Plaintiff repeats and realleges each and every allegation contained in the foregoing paragraphs as if fully set forth herein.

326. During the Class Period, the Individual Defendants participated in the operation and management of PolarityTE, and conducted and participated, directly and indirectly, in the conduct of PolarityTE's business affairs. Because of their senior positions, they knew the adverse non-public information regarding the Company's inadequate internal safeguards in data security protocols.

327. As officers and/or directors of a publicly owned company, the Individual Defendants had a duty to disseminate accurate and truthful information with respect to PolarityTE's financial condition and results of operations, and to correct promptly any public statements issued by PolarityTE which had become materially false or misleading.

328. Because of their positions of control and authority as senior officers, the Individual Defendants were able to, and did, control the contents of the various reports, press releases and public filings which PolarityTE disseminated in the marketplace during the Class Period. Throughout the Class Period, the Individual Defendants exercised their power and authority to cause PolarityTE to engage in the wrongful acts complained of herein. The Individual Defendants therefore, were "controlling persons" of PolarityTE within the meaning of

Section 20(a) of the Exchange Act. In this capacity, they participated in the unlawful conduct alleged which artificially inflated the market price of PolarityTE common shares.

329. By reason of the above conduct, the Individual Defendants are liable pursuant to Section 20(a) of the Exchange Act for the violations committed by PolarityTE.

VIII. PRAYER FOR RELIEF

WHEREFORE, Plaintiff demands judgment against Defendants as follows:

A. Determining that the instant action may be maintained as a class action under Rule 23 of the Federal Rules of Civil Procedure, and certifying Plaintiff as the Class representative;

B. Requiring Defendants to pay damages sustained by Plaintiff and the Class by reason of the acts and transactions alleged herein;

C. Awarding Plaintiff and the other members of the Class prejudgment and post-judgment interest, as well as their reasonable attorneys' fees, expert fees and other costs; and

D. Awarding such other and further relief as this Court may deem just and proper.

IX. DEMAND FOR TRIAL BY JURY

Plaintiff hereby demands a trial by jury.

Dated: April 2, 2019

Respectfully submitted,

POMERANTZ LLP

By: */s/ Jeremy A. Lieberman*

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CERTIFICATE OF SERVICE

I hereby certify that on the 2nd day of April, 2019, a true and correct copy of the foregoing **AMENDED CLASS ACTION COMPLAINT FOR VIOLATION OF THE FEDERAL SECURITIES LAWS** was served on counsel who have appeared electronically in this action.

/s/ Jon V. Harper